vital scientific

Preface

CE

This instrument **conforms to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998.**

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This manual was written and produced with the utmost care. However, errors cannot be fully excluded. Vital Scientific do not take any responsibilities and accepts no liabilities for incidents of any kind that may occur because of errors in the manual.
All product names are mentioned in this manual are registered trademarks. The manual describes the analyser system Vitalab Selectra E and the new software version (June 2003).
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Safety Precautions and Potential Hazards

1.1 General

Before you start installing and working with the analyzer, you should read the safety precautions and regulations shown in this chapter. Safety comes first!

The analyzer was designed and manufactured according to modern standards and with regard to international safety regulations. All possible risks that were known at the time of manufacturing were taken into account and either eliminated or reduced. Nevertheless, some sources of danger cannot be eliminated. Please note the following guidelines.

When operating the Vitalab analyzer all national or international guidelines and regulations must be observed, as in the normal lab routine. Power supply accessories (cables/plugs) must be installed in such a way that sources of danger (overheating of cables, short circuit due to incorrect fuse ratings, loose cables etc.) are eliminated. The user should be aware, that if the Vitalab analyzer is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

1.1.1 Disclaimer

Vital Scientific does not recommend any specific reagent kit or reagent supplier to be used in combination with this analyzing system. This instrument is designed as a 'open' system allowing for a wide range of clinical chemistry tests to be adapted to the system. As results obtained from a clinical chemistry system may vary depending upon the specific characteristics of the reagent kit involved, the test parameters for each test (and each reagent supplier), needs to be established by appropriate methods, before the system is used for actual measurements of patient samples. Vital Scientific N.V. assumes no responsibility for erroneous test results caused neither by the reagents and/or calibrators nor for inadequate use and determination of test parameters.

1.1.2 Operator Qualification

The analyzer should only be used by qualified and trained personnel, who have taken part in a special operator training course on the instrument.

For clinical tests, the instrument should be used under the management of a doctor or clinical inspector.

1.1.3 Service Technician Qualification

To install, maintain and repair the instrument, a service technician has to be trained on the instrument by the manufacturer or their representative. A service technician is also expected to be familiar with the normal operation of the instrument as described in the User's manual and the special operations as described in the Service manual.

1.2 Description of symbols

1.2.1 Symbols on the instrument

This symbol means that the labelled item is hot while the instrument is in use. Don't touch the labelled item as you could be burnt!

Attention, consult instructions for use. This symbol appears on several parts of the analyzer and the specific meaning of each of these symbols is described below.

1.2.2 Symbols in the manual

ATTENTION! Warning

Failure to follow information contained in warning messages could lead to serious personal injury and/or damage to the analyzer.

Note!

Notes contain additional information corresponding to the text.

1.3 Hazards

1.3.1 Electrical hazards

ATTENTION! Warning

To prevent the risk of electrical shock and/or damage to the instrument **Operators** should not open the covers of life parts (electrical) of the instrument. Only authorised personnel, for example, **service technicians,** may open the instrument to perform maintenance or repair.

Touching the life parts when the power is on may cause severe injury or death.

1.3.2 Mechanical hazards

ATTENTION! Warning

DO NOT wear loose garments or jewellery that could catch in mechanisms.

DO NOT put your fingers/hands into the pathway of any part while the analyzer is in operation.

DO NOT attempt mechanical repair unless the instrument is not in operation or OFF.

1.3.3 Sample and Reagent arms

ATTENTION! Warning

Do not touch movable parts of the system (rotors, arms, etc.) while they are in motion.

Particular attention and caution must be paid to sample and reagent needles. Although the greatest possible safety precautions were taken, these parts still are potentially hazardous. However, the system automatically interrupts the procedure if the needles are touched. Always keep rotors covered with the supplied caps, except when loading or unloading. Covering protects sample material and reagents from contamination.

1.3.4 Lamp

ATTENTION! Warning

During operation, the photometric lamp becomes extremely hot. DO NOT look directly into the light path of the lamp when it is on.

DO NOT touch the lamp when it is on!

If the lamp needs to be changed, wait until the lamp has cooled down. For details refer to the chapter 6, Maintenance, Troubleshooting and Error Messages in this manual.

1.3.5 Chemical hazards

The operator is responsible for taking all necessary precautions against hazards associated with the use of clinical laboratory chemicals. Specific recommendations for each reagent used with the analyzer are normally found on the manufacturer's package inserts or on product information sheets for each chemical. Wipe up any reagent spillage on the instrument immediately.

Additional precautions:

Consult the reagent manufacturer for information on the concentrations of heavy metals and other toxic constituents in each reagent.

Avoid direct body-contact with reagents. Direct body-contact may result in irritation or damage to your skin. Refer to the manufacturer's reagent kit box and package inserts, or product information sheets for specific instructions.

Avoid direct body-contact with cleaning solutions. Direct body-contact may result in skin irritation or damage. Refer to the manufacturers kit box and package inserts, or product information sheets for specific instructions.

1.3.6 Biohazard

ATTENTION! Warning

Controls, patient samples and liquid waste are potentially infectious. The handling of patient samples, control sera and liquid waste must be performed according to national and international laboratory safety regulations.

Specimens (patient samples and controls) and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimise risk to laboratory staff. This includes wearing of gloves, splash protection, etc. Contact of skin and mucous membranes must be avoided. This also applies to all components of the instrument that are exposed to these substances. If any specimen is spilt on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant.

In various countries there are regulations on the disposal of waste. Refer to local sources for additional information on correct waste disposal.

1.4 Installation and maintenance

The analyzer, cooling unit and other devices, parts and accessories are shipped in transport boxes and have to be unpacked and installed by a qualified service technician from the manufacturer or his designated representative. If these instructions are not observed, Vital Scientific N.V. does not assume responsibility for occurring damage or improper operation of the analyzer. The customer is responsible for providing the necessary facilities as described in detail in chapter 2.7: Operation requirements and 2.9: Performance and technical data.

1.4.1 External connections

ATTENTION! Warning

Only instruments that meet the relevant safety requirements may be connected to the analyzer.

1.4.2 Maintenance

ATTENTION! Warning

For continued protection against risk of fire only use fuses of the specified type and current ratings.

For maintenance and repair procedures (e.g. replacement of cuvette rotor, photometer lamp) follow the instructions given by service personnel or specified in the manual.

Do not use unsuitable tools for repairs (e.g. screwdrivers which are not insulated for work performed at electrical components).

During operation and maintenance of the instrument, proceed according to the instructions and do not touch any parts of the instrument other than those specified.

Avoid touching all mechanisms, i.e. sample needle, while the instrument is operating. This may cause operation to stop or damage the instrument.

Only original spare parts should be used in the maintenance of this analyzer.

Only original disposables and accessories should be used in the operation of this analyzer.

1.4.3 Instrument Unused for a Long Time

If the instrument will not be used for a long period of time, contact Technical Support for further information.

1.5 Use of materials with the analyzer

1.5.1 Specimens

This analyzer is designed for measurements of analytes in samples of serum, plasma, urine and CSF. Patient samples should be prepared and handled in accordance with the instructions from the reagent manufacturer. Refer to the reagent kit insert for detailed instructions.

1.5.2 Warning

Make sure that the sample/reagent mixture does not contain any blood clots, dust or other insoluble contaminants. If insoluble contaminants are contained in the sample, correct measuring values may not be obtained.

1.5.3 Reagents and calibrators

Vital Scientific N.V. does not recommend the use of specific reagents or calibrators in combinations with this analyzer. Several reagent manufacturers have application sheets available for a large variety of clinical chemistry tests. Therefore contact your local reagent supplier for the application sheets required.

1.5.4 Warning

ATTENTION! Warning

Treat all reagents according the manufacturer's recommendations. Refer to the reagent kit box and package inserts, or product information sheets for specific instructions.

1.5.5 Disclaimer

Vital Scientific N.V. assumes no responsibility for erroneous test results caused by reagent kits, calibrators and /or test parameters that are not provided by Vital Scientific N.V.

1.5.6 Controls

Vital Scientific N.V. recommends the use of quality control solutions with known values for each test in accordance with international regulations and guidelines. Results obtained should fall within the limits defined by the day to day variability of the system as determined in the user laboratory. If the results fall outside the laboratory's established limits, refer to the troubleshooting information in this manual or contact your agent.

1.5.7 Analytical results

The analytical results do not only depend upon correct operation of the analyzer but also on a variety of external influences beyond the control of the manufacturer. Therefore the test results obtained with this instrument must be carefully examined by an expert before any measures are taken based on the analytical results.

Warning

ATTENTION! Warning

An incorrectly measured result may lead to an error in diagnosis, thereby posing a danger to the patient.

Introduction

2.1 Intended use

The Vitalab analyzer is an automatic chemistry analyzer, used in combination with certain reagents for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine and aqueous standard solutions. The analyzer is designed as an ´open´ system. Most clinical chemistry tests that require a photometric measurement can be adapted on the system. The Vitalab analyzer is intended for use in clinical chemistry laboratories where the workload is of medium quantity. The analyzer has to be operated by trained professionals.

Disclaimer:
Depending on the specific characteristics of the involved reagent kit, the results obtained from a clinical chemistry system may vary. The test parameters for each test (and each reagent supplier), need to be developed by appropriate methods [for example using ECCLS* or NCCLS* guidelines] before the system is used for actual measurements of patient samples. Vital Scientific N.V. takes no responsibility for erroneous test results caused by reagent kits and/or test parameters that are not provided by Vital Scientific N.V.

* ECCLS = European Committee for Clinical Laboratory Standards
* NCCLS = National Committee for Clinical Laboratory Standards (USA)

2.2 System presentation

The Vitalab analyzer is a universal system. The price-performance-relation is optimized for small and medium workload (up to 180 tests per hour, or even up to 270 tests per hour when the optional ISE unit is used). It is easy to adapt the analyzer in any kind of laboratory.

In the main unit of the system, the actual analyzer, all liquid handling and measurements take place. A separate computer controls the analyzer unit, collects the raw data and provides the user interface. A cooling unit enables the system to ensure the precision of all ´on-board´ parameters. Environmental compatibility and economic efficiency are guaranteed. Easy operation (menu and message control by display), short training time as well as recording of sample and test data with barcode scanner reduce personnel assignment and save a maximum of time.

2.3 Analyzer

Note

In the screen texts system liquid is replaced by water.

The Vitalab analyzer is a PC-controlled clinical chemistry analyzer. It is designed as a random access full selective patient-oriented system. The test parameters for 55 different tests can be programmed. The analyzer can run simultaneously from 1 up to 26 tests. The analyzer has the following measurement capabilities:

In the dual mode:

- Reagent absorbance (bichromatic) before sample addition.
- Kinetic 1 during 4,5 minutes after sample addition (can be used as slope blank for kinetic 2)
- Kinetic 2 during 4 minutes after reagent 2 addition.
- Kinetic 1 + 2 during 8.5 minutes after sample addition.
- Sample blank (bichromatic) before reagent 2 addition.
- End point (bichromatic) before reagent 2 addition.
- End point (bichromatic) 4.5 minutes or 11.5 minutes after sample addition or 6.5 minutes after R2 addition.
- Kinetic 1, kinetic 2 and kinetic 1 + 2 can contain a minimum measuring time or two points for two point measurements.

In the mono mode:

- Reagent absorbance (bichromatic) before sample addition.
- Kinetic during 7 minutes after sample addition.
- End point (bichromatic) 11.5 minutes after sample addition.
- Kinetic can contain two points for two point measurements.

The different reagents are placed in a cooled reagent rotor. A pipette injects the reagents directly into the reaction cuvettes. The cuvettes are incubated at 37°C, measured at the selected wavelength and washed for re-use. Bichromatic measurements are possible for endpoint chemistries.

The cycle-time in the mono-reagent mode is 20 seconds, in which the analyzer can do up to 180 tests/hour (with the optional ISE unit 270 tests/hour). The cycle-time in the dual-reagent mode is 27 seconds, in which the analyzer can do up to 133 tests/hour (with the optional ISE unit 222 tests/hour). Emergency and pediatric samples can be tested without interference of the routine workload.

The Vitalab analyzer is microprocessor controlled. All mechanical functions are driven and checked by slave-processors. The operator has a constant view on the hardware status and performance of the chemistries. When errors or flagged results occur, the Vitalab Analyzer offers an automatic re-run facility. The re-run facility includes automatic sample reduction for high results. The results are printed patient-oriented and in the analysis sequence. The print is held when a test is in evaluation or re-run. This prevents mixing-up the analysis sequence. The operator can change the format of the result report. Prints of calibration curves, reaction curves, Levey-Jennings plots, test methods, etc. are possible.

2.3.2 Sample rotor

The positions in the sample rotor:

1	Blank
9	Calibrators
51	Samples (can also be used for controls en calibrators)
6	Pediatrics (in case of the optional ISE unit, one position is in use for the ISE activator).
3	Emergencies
4	Controls
1	Wash solution

All positions can contain primary tubes and Terumo 5 ml tubes. Also adapters for low volume containers are supplied. An optional rotor for Kabe or Sarstedt 5 ml sample tubes is available. The sample rotor is covered.

Sample pipette mechanism

The sample probe, equipped with a level detector, aspirates any volume between 1µl and 30 µl (in steps of 0,1 µl). The probe dispenses it into the cuvette rotor and also mixes the reaction mixture. Before sensing the sample the sample probe will take up an air bubble first. The probe is washed in- and outside afterwards.

2.3.3 Reagent rotor

Note

For optimum cooling and to avoid waste of energy, cover unused positions during a test with caps. The caps also prevent evaporation of the reagents.

The positions in the reagent rotor:

24	bottles of 25 ml (or up to 5 bottles of 50 ml; a 50 ml bottle takes 2 positions of 25 ml bottles)
8	bottles of 8 ml

The reagent rotor compartment is cooled to approximately 12°C below ambient temperature. The rotor is covered to protect light sensitive reagents and to isolate from ambient temperature.

Reagent pipette mechanism

The level detector in the reagent probe detects if sufficient reagent is present. A heating element in the probe pre-heats the cooled reagents. Reagents must be prepared outside the analyzer. After the probe transferred the aspirated volume of reagent into the cuvette rotor, the probe is washed in- and outside. After a 2nd reagent is dispensed, the reagent probe mixes the reaction mixture.

2.3.4 Pipettes

Two syringes, a 1000 µl and a 100 µl, are used in combination with a valve block to pipette reagents and samples. The pipette mechanisms are water-filled. Reagents and samples are aspirated with air bubble separation.

2.3.5 Cuvette rotor

Note

Replace the cuvette rotor when one of the eight wavelengths prints the message **SD.ERR** after the rotor blank measurement. The quality and reliability is not guaranteed when the cuvette rotor is not replaced.

The multi-use cuvette rotor contains 48 cuvettes, incubated at 37°C. The path length is 6.8 mm and the minimum measuring volume is 220 µl. The cuvette rotor, special made for Vital Scientific, is covered by a heated cover.

The rotor makes in the mono mode a complete revolution plus one extra step every 20 seconds. In mono mode the analyzer can measure 22 kinetic points, an endpoint and a reagent blank at any of the 8 available wavelengths during a revolution. The rotor makes in the dual mode a complete revolution plus one extra step in 27 seconds. In dual mode the analyzer can measure 21 kinetic points, an endpoint and a reagent blank at any of the 8 available wavelengths during a revolution. In both cases, the value of the reagent blank is used for various checks and the measurement of the endpoint can be bichromatic.

The maximum incubation time after sample addition is 11.5 minutes in mono mode and 11,25 minutes in dual mode. The first kinetic point in the mono mode can be measured after 12 seconds, the last after 422 seconds. In the dual mode the first kinetic point can be measured after 24 seconds, the last after 519 seconds. After the last measurement, the rotor is washed and dried. To avoid drying-in of the rotor, the reagent probe automatically fills the rotor with water.

2.3.6 Washing unit

The washing unit aspirates the reaction mixture after analysis and washes the cuvettes with 4 x 500 µl water. The waste is disposed in a waste container. Separated waste, concentrated and diluted in two containers, is available (ex-factory option only). The washing unit is equipped with liquid sensors to avoid flooding the system with water.

2.4 Computer control

Note

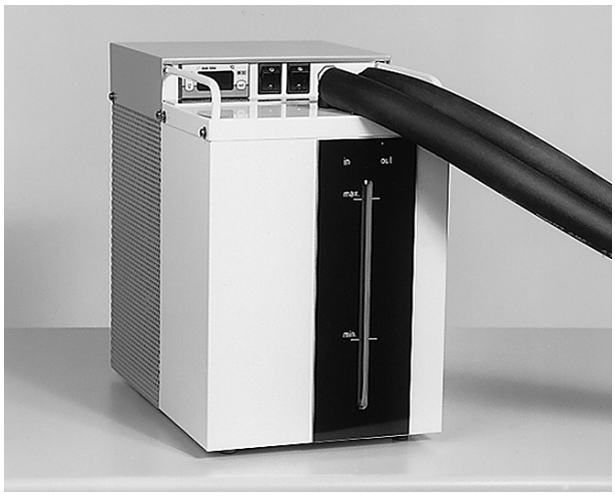
Only run the software in order to operate the analyzer. The use of other software might cause failure in the communication between the analyzer and the computer.

An external computer provides the user interface to the analyzer. The software is Windows-based to save a maximum of time. A keyboard or a barcode reader is necessary to enter data. The test results are saved on the computer. The software provides a standard way of output on a printer, but the operator can change the format of the result report. Test parameters, control results and calibration results are also saved on the computer and ready for access any time.

It is possible to connect the analyzer to a lab data processing system (central processor/host computer). If so, it is possible to enter test requests directly from the host computer. Also the test results can be transferred to the host computer.

2.5 Cooling unit

The analyzer is equipped with an external cooling unit. The cooling unit provides a constant temperature of the reagents located on the rotor, keeping them fresh (as required by the application prescription). When an acoustic signal is heard, the cooling liquid must be refilled. The control display shows the temperature of the cooling liquid. The actual temperature of the reagents will be slightly higher. The user cannot change the temperature setting of the cooling unit.

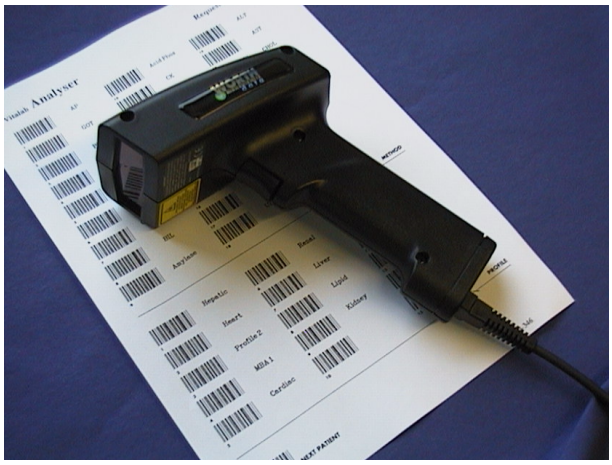


2.6 Barcode reader

Caution

Switch off the computer before you install the barcode reader.

The barcode reader can be connected to the keyboard of the external PC. The reader is used for test requisition and randomized loading of the samples. Most of the available barcodes can be read, but Codabar gives the highest convenience. The Codabar start character is used to differentiate between tests and profiles.



2.7 Operation requirements

Only a qualified service technician may unpack the analyzer, cooling unit and other devices. Vital Scientific N.V. does not take responsibility for damage or improper operation of the analyzer, when these instructions are not observed. The analyzer is inspected and ready for use when it is handed over to the user.

Use the analyzer in closed rooms. It must be placed on a flat, horizontal surface that is not subject to vibrations. Avoid exposure to direct sunlight.

The electrical connection has to be grounded according to common regulations, to ensure proper operation of the analyzer.

The analyzer is compliant with the requirements of the applicable EMC standards. Electronic equipment that exceed the radiation limits defined in the EMC standards, like GSM and other handheld mobile equipment, may affect proper operation of the equipment.

Note

This is a class A product. This product may cause interference in a domestic environment. In this case the user may be required to take adequate arrangements.

2.8 Move the analyzer

Please follow the instructions below when the instrument needs to be moved over a larger distance:

1. Switch off the analyzer, the computer and the cooling unit.
2. Disconnect all cables and tubes.
3. Remove the door of the syringe compartment by lifting it when fully opened.
4. Pull up the arms and place the arm protection tubes over the shafts. The arms are prevented from going down.
5. Move the analyzer with at least 2 persons. Hold the instrument only by the metal frame on the bottom.
6. Connect all cables and tubes again when the analyzer is in place.

2.9 Performance and technical data

Performance

Throughput	MONO MODE: 180 tests per hour (270 with optional ISE unit) DUAL MODE: 133 test per hour (222 with optional ISE unit)
Accuracy	Refer to note 1
Precision	Refer to note 1
Programmable tests	55 per programmed reagent disc
Loadable tests	32
Quality control	3 per parameter, 15 controls programmable per reagent disc
Sample processing	Entirely selective sample-oriented
Sample volume	1 to 30 µl per test

Sample system

Sample positions	51 patient samples
Emergency samples	3 positions
Calibrators	9 positions plus max. 51 patient sample positions
Pediatric samples	5 positions
ISE position	1
Blank position	1
Controls	4 positions plus max. 51 patient sample positions
Rinsing position	1
Sample tubes	Primary/secondary tubes Diameter: 13-16 mm Height: max. 73 mm
Sample needle	With level detector and integrated mixer
Pipetting capacity	1-30 µl (steps of 0.1 µl)
Syringe	100 µl
Adapter	6 (pediatric, sample rotor)

Reagent system

Reagent rotor	32 positions: 24 × 25 ml, 8 × 8 ml and 5 × 50 ml bottles possible
Volume/test	Reagent 1: 110 – 399 µl, reagent 2: 0, 10 – 180 µl
Cooling	Up to 12 °C below ambient temperature
Needle	Pre-heated, with level detector and integrated mixer
Pipetting capacity	400 µl (steps of 1 µl)
Syringe	1000 µl
Adapter	8 (for 8 ml bottle in 25 ml position)

Measurement Station

Cuvette rotor	Multi use disposable rotor with 48 positions
Path length	6.8 mm
Minimum volume	220 µl
Wash station	fully automatic with overflow-level detector
Cuvette rinsing	4 × 500 µl system liquid
Light source	Halogen lamp 12V 20W
Wavelength	340, 376, 405, 436, 505, 546, 578, and 620 nm
Wavelength uncertainty	+/- 2 nm
Spectral half-width value	10 +/- 2 nm
Measuring range	-0.1 to 3.0 Abs.
Temperature	37 °C ± 0.2 °C
Cycle time	20 sec. (MONO MODE) 27 sec. (DUAL MODE)

Minimum PC Requirements

CPU	Intel Pentium 133 MHz
RAM	32 MB
Monitor	VGA Monitor 640 x 480 pixel
Hard Disk	1 GB
Floppy Disk drive	3.5” (1.44 MB)
Additional drive	CD-ROM drive
Operating system	Windows 98 Second Edition or 2000
Serial ports	1 for analyser, 1 for host*, 1 for printer 2*
Parallel port	1 for printer
	* depending on options used

Cooling unit

Weight (empty)	19.6 kg
Weight (filled)	Approx. 23 kg
Required space	84 cm²
Dimensions (cm)	24W × 37H × 35L
Coolant	3.5 l, glycol-based
System	Closed circulation
Connection	Mains connector
Power consumption	340 VA max.
At operating voltage	110 or 230 VAC (device-dependent)
Line frequency	50/60 Hz

Barcode reader

Version	Hand device
Technology	CCD
Barcodes	UPC-A +2, +5 UPC-E +2, +5 EAN-13 +2, +5 EAN-8 +2, +5 Code 39 Code 93 Code 128 Codabar Code 2 out of 5 Code 2 of 5 interleaved MSI/Plessey

Note 1: Accuracy and precision

The chemical performance of clinical chemistry analyzers, in terms of accuracy and imprecision, depend on the following: the characteristics of the instrument; the measurement techniques and the materials used. Therefore, the chemical performance characteristics of a clinical chemistry analyzer can only be established and postulated in terms of: the analyte; the specific reagent kit and calibrator(s) used; the type and constitution of the specimens involved; etc.

The Vitalab analyzers are designed as open systems. ´Open´ implies that most clinical chemistry tests and techniques that require photometric measurement, can be adapted on the system. Only the test parameters for a specific test need to be adjusted. The user needs to establish the required test parameter settings to achieve satisfactory results, utilizing appropriate methods. The methods are preferably based on international guidance documents, for example ECCLS or NCCLS guidelines.

Vital Scientific N.V. does not suggest or propose any particular reagents, calibrators and/or controls on their analyzers from a specific manufacturer. Obtain information on the performance characteristics from the selected reagent distributor and/or manufacturer. Various reagent manufacturers have performed performance studies on the Vitalab series in combination with their reagent kits. Therefore, they have application sheets available for various analytes. The required information usually can be obtained from the reagent package inserts. Please contact your local representative and/or reagent manufacturer for further information on the chemical performance of their reagents on Vitalab analyzers.

Disclaimer

Vital Scientific N.V. assumes no responsibility for erroneous test results caused either by the reagent kits and/or calibrators or for inadequate use and determination of test parameters.

2.9.2 Analyzer Technical Data

Dimensions and weight

Width	115 cm
Depth	56 cm
Height	49 cm
Weight	Approx. 85 kg

Power requirements

Line Voltage	110/240 V nominal, tolerance 10%
Line Frequency	50/60 Hz
Power Consumption	320VA
Installation category	II (in accordance with IEC664)

Environmental requirements

Ambient temperature	15 to 32 °C
Max. relative humidity	85 % RH max.
Pollution degree	2 (in accordance with IEC 664)

System Handling Basics

3.1 Work Preparation

Read this chapter carefully before you start working with the analyzer. Always observe the safety instructions, in order to prevent accidents.

Note

In this manual, the dilution ratios are given as parts of the sample to parts of the resultant solution. Thus, a dilution ratio of 1:5 means 1 part of the sample diluted with 4 parts of diluent that results in 5 parts of solution.

3.1.1 Manual Use

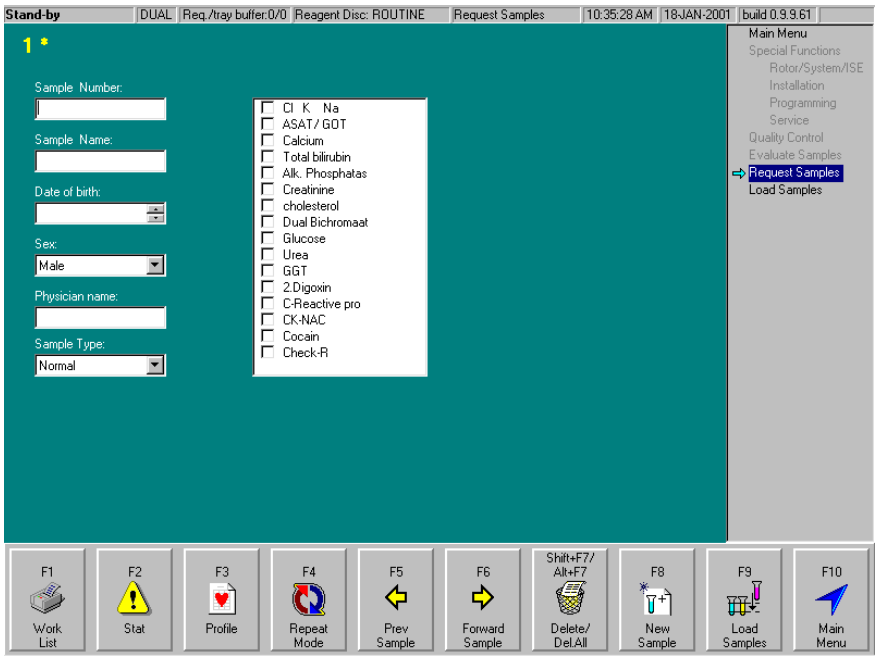
Each chapter that describes the operation of the analyzer contains a function section followed by an example. The function section contains information about key and field functions available in the menu structure. The example gives clear explanations and instructions.

Example for a function section "Recording of Sample Requests"

SAMPLE NUMBER — 12 characters (letters and numbers) are available for the sample number. To increase the sample number by one for the next request you can select the automatic increase checkbox in the **SYSTEM PARAMETERS** menu.

F2 STAT — The request displayed on the monitor is marked as an emergency sample (Stat).

When an example follows the function section, the example describes the method of the procedure. In this case, the necessary steps to record a patient's sample and to request a sample test are explained and illustrated.



Example

Before you start manual recording always enter the sample number at the parameter **Sample Number**, otherwise no analysis can be made. Enter further patient data or move directly to test the Request Samples by pressing the **TAB** key or by using the mouse.

3.1.2 Menu structure

The analyzer software is menu driven. All the functions are accessed from the **MAIN MENU**. The following diagram shows the main functions.

MAIN MENU
F5 Special Function
F6 Quality Control
F7 Evaluate Samples
F8 Request Samples
F9 Load Samples

F5 SPECIAL FUNCTIONS
F1 Rotor/System/ISE
F2 Installation
F3 Program
F4 Service
F6 Quality Control
F7 Evaluate Samples
F8 Request Samples
F9 Load Samples
F10 Main menu

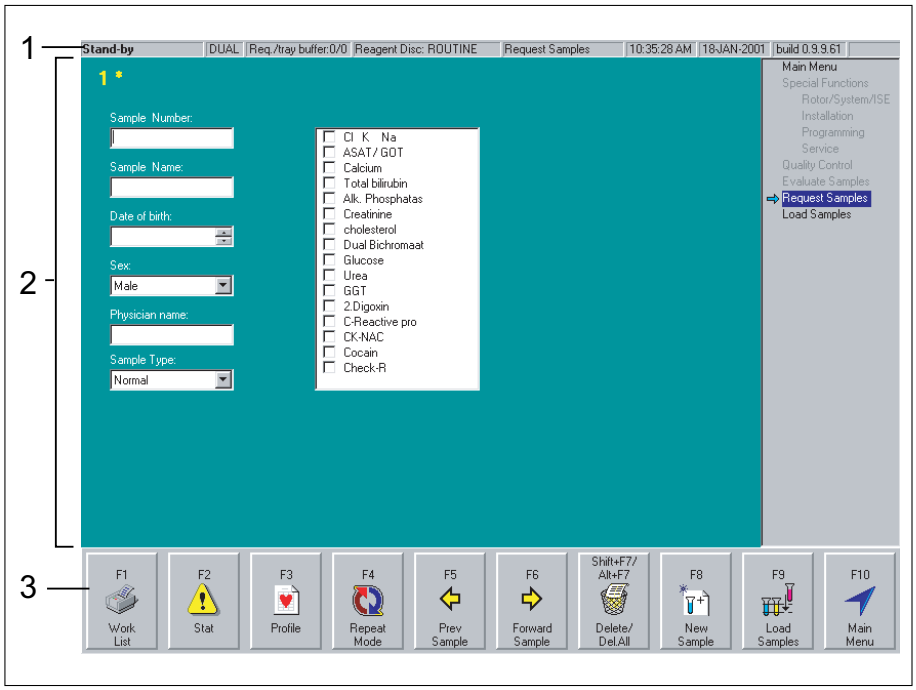
F6 QUALITY CONTROL
F4 Program Control
F6 Graphic Mode
F7 Evaluate Samples
F8 Request Samples
F9 Load Samples
F10 Main Menu

F7 EVALUATE SAMPLES
F1 Print
SF2 Clear Res. Buffer
F3 Blank/Calibrator Info
SF4 Cancel Request
F5 Evaluate Disk Samples
F6 Quality Control
F7 Graphic Mode
F8 Request Samples
F9 Load Samples
F10 Main Menu

F8 REQUEST SAMPLES
F1 Load List
F2 Stat
F3 Profile
F4 Repeat Mode
F5 Prev. samples
F6 Forward Sample
SF7 Delete
AF7 Delete All
F8 New Sample
F9 Load Samples
F10 Main Menu

F9 LOAD SAMPLES
F1 Load List
F2 Select Unload
F3 Confirm Unload
F5 Reagent Info
F6 Quality Control
F7 Evaluate Samples
F8 Request Samples
F9 Update
F10 Main Menu

3.1.3 Parts of the screen



1. Status line
2. Input area with functions
3. Function keys **F1** to **F10**

Status line

The information on the status line does not depend on current system operation. The status line shows following information:

- Status of the analyzer, e.g. **Stand-by**.
- Run Mode: **Mono Mode** or **Dual Mode**.
- Request Buffer: information about the number of samples that is requested but not yet loaded
- Tray Buffer: information about the current number of sample tubes loaded into the analyzer.
- Reagent disc: Name of the selected reagent disc.
- Display mode: the menu in which you are currently working, e.g. **MAIN MENU**.
- Time and date
- The state of the external interface (RS 232), e.g. **On-line**.

Input area

To input data and to select the functions and menus use the keyboard or mouse. To read the sample labels and tests on the barcode tray use the barcode reader.

Function Keys F1 to F10

Information of the specific function of the function keys is on constant display on the monitor. All displays have a common structure with the Function Keys at the bottom of the monitor.

3.1.4 Keys

ARROW KEYS	Go to another field
TAB	Switch between left and right fields
PAGE UP/DOWN, HOME, END	Scroll through a list
ENTER	Confirm entry
F1 – F10	Function keys
ALT+F10	Emergency halt
SPACEBAR	Select or deselect a checkbox

Note

To stop the whole analyzer, press ALT+F10 simultaneously. This emergency stop is always possible. The analyzer goes to the Halted state and all current measurements are lost. You can repeat these measurements afterwards.

3.1.5 Messages

If an error occurs in the analyzer or the operation routine, the analyzer displays an error message on the monitor. The message is accompanied by an acoustic signal. The message gives information about the error and, where possible, instructions how to solve it.

Example:
E12 water running out shows when the analyzer liquid is low. You must fill the water container. The analyzer will continue the interrupted operation without further consequences. Refer to "Messages" in chapter 4.

3.2 Start the analyzer for the first time

Warning

Do not install the analyzer yourself. The analyzer must be installed by trained personnel.

After installation and before you can use the analyzer in normal routine operation, several system adjustments must be made.

3.2.1 Prepare the analyzer

Do following operations in this sequence:

1. Start the analyzer. Refer to 3.2.2.
2. Install PC and analyzer software. Refer to chapter 7.
3. Connect the cooling unit. Refer to chapter 3.2.5.
4. Fill the system with system liquid. Refer to 3.2.6.
5. Set up the system parameters and the run mode. Refer to 3.2.3 and 3.2.4.
6. Program the calibrators. Refer to chapter 5.
7. Load or program the test parameters. Refer to chapter 5.
8. Program the controls. Refer to chapter 5.
9. Define the incompatible tests. Refer to chapter 5.
10. Program the profiles. Refer to chapter 5.
11. Position the reagents. Refer to chapter 5.

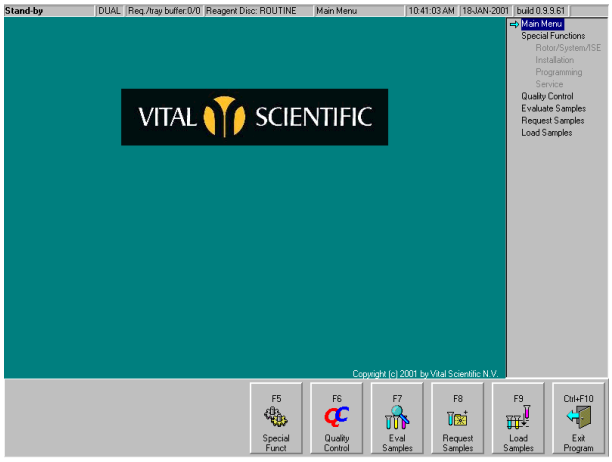
3.2.2 Start the analyzer

1. Set the main switch to ON, located on the rear panel of the analyzer.
2. Set the PC to ON.
3. Start the analyzer software. The main menu appears on the monitor.

When the analyzer remains on, but is not active carrying out processes, the analyzer goes to **Stand-by mode**.

4. Set the **SYSTEM PARAMETERS** and the **RUN MODE** menus. You must set these parameters before you can prepare the analyzer for the initial routine (e.g. programming of test parameters and controls).
5. Fill the analyzer with system liquid. Use the **SPECIAL FUNCTIONS** menu.

The analyzer is now ready for operation.



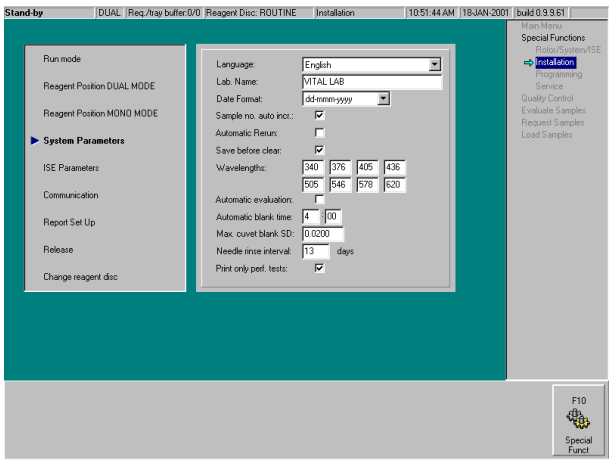
Note

When the analyzer has been switched off after the last routine was finished, you must start a manual cuvette blank measurement when you switch on the analyzer again the next morning. You can select this measurement in the **SYSTEM PARAMETERS** menu.
All data present in the analyzer are stored when the device is switched off.

3.2.3 Set the System Parameters

1. Select **F5 SPECIAL FUNCTIONS, F2 INSTALLATION**. The **SYSTEM PARAMETERS** menu is shown.
2. Enter the system parameters. Use the cursor keys or the mouse to select the parameters. Enter the value and confirm with **ENTER**.

Normally enter these parameters only once before the analyzer goes into operation. However, you can change the parameters whenever necessary, e.g. the date format.



Parameters

Language — Select the language used.

Lab. Name — Type the name of the laboratory. The field is 32 characters in size. The name is shown on every result printout.

Date Format — Select the date format. The date is shown on the monitor and on every printout:

dd-mmm-yyyy	e.g.	13-JUN-2000
mmm-dd-yyyy	e.g.	JUN-13-2000
dd-mm-yyyy	e.g.	13-06-2000
mm-dd-yyyy	e.g.	06-13-2000

Sample no. auto incr. — ☒ Select the sample counter to automatically increase the sample number in the **REQUEST SAMPLES** menu, when patient samples are recorded. Alphanumeric data is always counted up. The analyzer counts the sequence e.g. from Az99 up to Ba00.

Automatic Re-run — ☒ Select the automatic rerun to automatically schedule a test with the rerun parameters of the respective test when the defined limits are exceeded. The rerun applies to the following cases:

- Linearity error
- Absorbance limit error
- Reagent deviation error
- Substrate depletion error
- Prozone error

The rerun is done with the defined rerun parameters. Limits and volumes of each parameter are set in the **SPECIAL FUNCTIONS, PROGRAMMING, TEST PARAMETERS** menu.

Save before clear

☒ The analyzer automatically saves the result data on hard disk before clearing the main memory.

☐ All result data will be lost and replaced by new data.

Data in the main memory is automatically deleted if the storage capacity is exceeded or when reagents have been positioned on the reagent rotor.

You can also manually delete the main memory with **ALT+F2** (**Clear Result Buffer**) in the **EVALUATE SAMPLES** menu.

Wavelengths — The eight wavelengths of the interference filters, displayed as nanometer

values.

Only change this parameter if new filters have been installed.

Automatic evaluation

☒ The analyzer automatically prints out all results. Invalid results are marked as **Reject**.

☐ The analyzer blocks the patient's results with one or more error messages, until you accept or reject these results in the **EVALUATE SAMPLES** menu. The results are then printed out.

Automatic blank time

The time (hh:mm) at which the analyzer will do every day an automatic blank measurement of the cuvette rotor. Enter the hours, press **ENTER**, enter the minutes and press **ENTER** again.

This measurement is only possible when the analyzer is in stand-by mode. If the analyzer is switched off, you must start this measurement manually each day.

It is recommended to do this measurement before the daily routine. After the measurement the analyzer prints a list with the following information:

- Blank date/time
- Blank results
- Number of days left up to the calibration of the respective method
- Number of days left up to the next needle rinse
- Number of days left up to the next system cleaning

If you do not do this measurement, the analyzer can continue to run. In case of an expired calibration, the analyzer will use the last calibration data until a new calibration is executed.

Max. cuvet blank SD

The maximum standard deviation tolerated by the analyzer in a blank measurement of the cuvette rotor. The recommended value is 0.0200. If this deviation is exceeded, an error message is printed out together with the rotor blank results.

Needle rinse interval

The interval in days, at which you do a needle rinsing.

0: No needle rinsing

1: The rinsing must be done each day

2: The number of days after which rinsing must be done

It is recommended to enter **7** days and to perform the rinsing at the end of the working week. Activate the **Needle Rinse** function in the **ROTOR/SYSTEM** menu.

Print only perf. tests

Only available when using report set-up, -Only prints the tests and the test results, if you request the tests in the request sample menu.

Keys

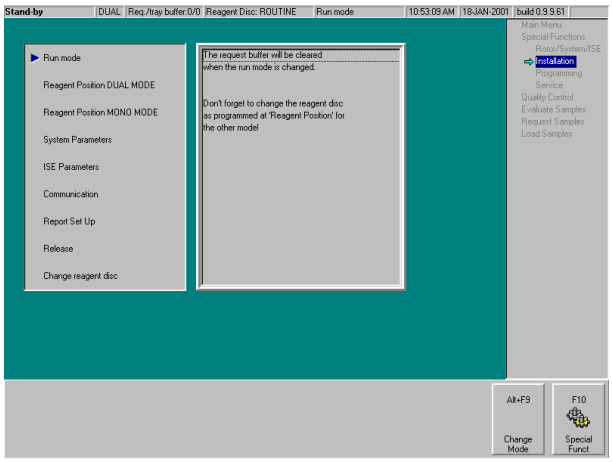
F10 Go to the **SPECIAL FUNCTIONS** menu.

3.2.4 Set the Run Mode

Note

All existing requests are cancelled when you change the run mode. The reagent positions must be defined separately for both modes. Also the result memory is cleared when changing modes.

1. Select **F5 SPECIAL FUNCTIONS, F2 INSTALLATION**.
2. Select **Run Mode**.
3. Press **ENTER** or **TAB**.



Keys

ALT+F9	Toggles between **Run Mode**.
F10	Go to the **SPECIAL FUNCTIONS** menu.

3.2.5 Install the Cooling Unit

Caution

Check the cooling unit for the correct voltage before you connect the cooling unit.

Never let the cooling unit pump run dry, because this will damage the pump.

The additional external cooling unit of the analyzer guarantees necessary cooling for loaded reagents. The cooling unit operates with a sealed cycle technology. The cooling unit requires virtually no maintenance. Unit and coolant are free from CFC.

Fill the unit with coolant and demineralised or distilled water before you put the analyzer in operation. Only refill the coolant in large intervals, since the coolant circulates in a closed liquid cycle. Refill the liquid if the LED flashes and/or an acoustic signal is heard.

1. Attach the connection tubing to the cooling unit and analyzer as shown in the figure.
2. Install the power cable to the back of the unit. The unit can run with either 110 or 230 V (device-dependent).

3. Switch on both switches on the front of the cooling unit before you switch on the analyzer.

Recommendations to ensure a steady cooling of the reagent rotor:

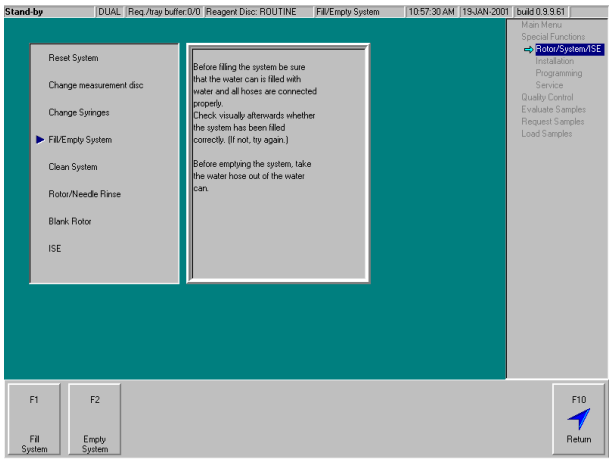
- Constantly keep the unit in stand-by mode.
- Cover the unloaded rotor positions with the supplied caps.

3.2.6 Fill/Remove System Liquid

To prepare the analyzer for operation, you must fill the entire liquid system with water.

Use this menu to make sure that the analyzer is filled with water. Also use this menu when you must remove water from the analyzer, e.g. for transport purposes.

Fill the water container with 25 ml of system liquid and 10 l of distilled or de-ionized water. Use water with a conductivity of less than 30 µS and a microbial count of less than 10 CFU/ml. For transport preparation empty the analyzer liquid container and the waste container(s).



Fill System

1. Select **F5 SPECIAL FUNCTION, F1 ROTOR SYSTEM, FILL/EMPTY SYSTEM**. Follow the instructions displayed on the screen.
2. Press **F1 FILL SYSTEM**, to start filling the analyzer with system liquid.
3. When the filling is complete, make sure that the tubing (e.g. tubing of sample probe or reagent probe) is filled with system liquid without air bubbles.
4. If you detect any air bubbles, press **F1** to repeat the procedure.

Empty System

1. Remove the system liquid hose from the water container.
2. Select **F5 SPECIAL FUNCTION, F1 ROTOR SYSTEM, FILL/EMPTY SYSTEM**. Follow the instructions displayed on the screen.
3. Press **F2 EMPTY SYSTEM** to empty the analyzer for transport.
4. Make sure that there is no system liquid left in the tubing.
5. If necessary, press **F2** to restart the emptying. The remaining waste must be removed after the procedure has been completed.

3.2.7 Operation Prerequisites

Observe the following prerequisites before going into operation.

Warning

Always observe the common safety precautions (rubber gloves, splash-protection).

Caution

Check the cooling unit for the correct voltage before you connect the cooling unit.
Never let the cooling unit pump run dry, because this will damage the pump.

Power supply, system stand-by mode (**as needed**)	Connect the system cables correctly. Switch on the analyzer. The monitor must show the **Standby** mode.
Cooling unit	Fill the cooling unit correctly with coolant. Install the tubing of the analyzer unit correctly. Switch on the cooling unit. Regularly check the liquid level visually.
System parameters (first installation and as needed)	Select the **INSTALLATION** menu, **RUN MODE** submenu. Make all necessary settings. Change the parameters in the **SYSTEM PARAMETERS** accordingly, if another printout is required or if a host computer is connected to the analyzer.
Liquid system (first installation)	Fill the liquid system of the analyzer with system liquid, when the system is put into operation for the first time. Use the **FILL/EMPTY SYSTEM** menu.
Programming calibrators (first installation and as needed)	Program the calibrators to be used by the system in the **CALIBRATORS** menu.
Programming controls (first installation and as needed)	Program the controls in the **CONTROLS** menu.

Programming test parameters (first installation and new parameters)	Load or program all parameters that are regularly used by the analyzer. Use the **TEST PARAMETERS** menu. This also applies to new tests that must be added. The programming instructions (e.g. test method, volumes, units etc.) are explained in the method sheets of the reagents.
Incompatibility of tests (first installation and new parameters)	Certain tests must not be run in succession, since the danger of carry-over is very high. Select the tests not to be run in succession in the **TEST INCOMPATIBILITY** menu.
Reagent positioning and reagent volume	All reagent positions on the reagent rotor that are currently used must be programmed in the analyzer. Use the **INSTALLATION** menu.
(daily and as needed)	In order to avoid delays in routine operation, it is recommended to check the volumes of the loaded reagents daily (**Reagent Info**). If the analyzer is run both in the **Mono Mode** and in the **Dual Mode**, the required reagent positions must be programmed separately for both modes (**REAGENT POSITION MONO MODE** menu and **REAGENT POSITION DUAL MODE** menu).
Programming profiles (as needed)	Select the profiles in the **PROFILES** menu, if you want to use profiles for the recording of patient samples. If the analyzer is run both in the **Mono Mode** and in the **Dual Mode**, the required profiles must be programmed separately for both modes (**REAGENT POSITION MONO MODE** menu and **REAGENT POSITION DUAL MODE** menu).
Water/Waste container (daily)	It is recommended to empty the waste container and to fill the water container before you start the daily work. Thus you avoid interruption of the routine work. The analyzer stops the operation, if the water level is too low or the waste water too high. The analyzer continues again when the required liquids are filled up or emptied.
Cuvette blank measurement (daily)	Do a cuvette rotor blank measurement once every day. This measurement is carried out automatically, if the respective settings have been made in the **SYSTEM PARAMETERS** menu. For this purpose, the system has to be in stand-by mode. Use the **BLANK ROTOR** menu for a manual start of the analyzer.
Sample preparation and safety precautions (daily)	In order to facilitate the work and to avoid interruption of the routine, the received samples must be prepared according to the respective lab organization instructions.

3.2.8 Checklist for Routine Operation

You can use the following list to check whether all prerequisites for operation of the Vitalab analyzer and the optional ISE unit are fulfilled.

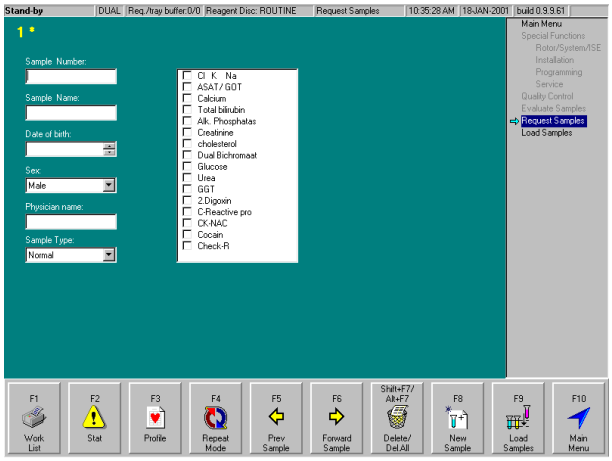
✓	**Are all cables correctly connected to the System ?**	Voltage cables, tubing to cooling unit, communication cables, etc.
✓	**Is the system switched on?**	Analyzer unit, computer and cooling unit: all switches “On”.
✓	**Are all necessary parameters defined?**	Run mode, language, print output type and host connection (if applicable).
✓	**Is the liquid system filled with system liquid?**	
✓	**Were all work helps set as required?**	Increase of sample number, automatic rerun, automatic result evaluation, automatic cuvette rotor blank, profiles.
✓	**Were all necessary test parameters programmed?**	Photometry.
✓	**Are all reagents correctly positioned?**	Reagent rotor.
✓	**Were all required calibrators defined?**	
✓	**Were all required test controls defined?**	
✓	**Were the incompatible tests defined?**	
✓	**Has the cuvette rotor blank been carried out?**	Cuvette Blank report.
✓	**Is a sufficient amount of system liquid in the system?**	Water container, syringes.
✓	**Has the waste container been emptied?**	Waste container(s).
✓	**Was formation of foam avoided during reagent preparation?**	Reagent bottles.
✓	**Was formation of foam avoided during sample preparation?**	Sample tubes.

Basic Routine

4.1 Entering sample data and test requests

4.1.1 Requests Samples menu

The **REQUEST SAMPLES** menu (**F8**) contains all parameters for test requests and entry or assignment of patient samples. You can quickly and easily enter sample and patient-specific data and request the designated tests. Recorded samples can later be edited or deleted. If needed, the analyzer prints a work list.



You can shorten the recording time with a barcode reader. A difference must be made between recording with barcode in the **REQUEST SAMPLES** menu and recording with barcode in the **LOAD SAMPLES** menu. You can scan the sample data from barcode labels on request forms. The tests are recorded with the barcode request chart. In the **LOAD SAMPLES** menu you can directly record data from the barcode labels on the sample tubes (primary tubes).

Parameters

If you requested a calibrator, a control or a blank sample, you can go directly to **Sample Type**. Use the **ARROW DOWN** key or the mouse.

Request Number

A request number is automatically assigned to each sample that is requested. The request number is shown on the top left. The request number indicates the place of the sample in the request buffer. An asterisk indicates a new request that is not saved yet.

Sample Number

Enter the sample number. Twelve characters are available (letters and numbers). If the checkbox **Sample no. autom. incr.** of the **SYSTEM PARAMETERS** menu was selected, the analyzer automatically increases the number entered here by one for each following test request. You can also record the sample number with the barcode on the request form.

If no number is entered for a patient sample the request will not be accepted.

Sample Name*

Enter the patient name or any other form of identification for the sample. Maximum length: 20 characters.

Date of birth*

Enter the date of birth of the patient, if the evaluation of the tests is patient-oriented. The entry form depends on the definition in the **SYSTEM PARAMETERS** menu.

Sex

Select the sex of the patient. Use the drop-down list or press **M** (Male), **F** (Female) or **P** (Pediatric). The analyzer uses the specified sex to compare the results to the respective reference values in the **TEST PROGRAMMING** menu.

Select **Pediatric** for samples of children. **Pediatric** is normally used for children up to the age of 14, but this also depends on the patient and the test to be done.

Physician name*

Enter the name of the physician in charge who ordered the test or sample. The default content of **Physician name** is the last entered

name. You can include this name in the data that is sent to a host. The system parameter is set in the **SPECIAL FUNCTIONS**, **INSTALLATION** menu. Maximum length: 20 characters.

Sample Type

Select the type of sample that is needed:

- **Normal**
  Normal patient sample. The analyzer automatically positions on the outer two rings of the sample rotor. The analyzer can process a maximum of 51 normal patient samples at one time, without having to reload the sample rotor.
- **STAT**
  Emergency sample. You can process a maximum of three Stat samples in one workload (E1...E3). The analyzer positions these samples on the provided positions on the outer rings of the sample rotor. The analyzer processes the Stat samples before all other samples.
- **Pediatric**
  Samples of children and teenagers. For a pediatric sample, you must select **Pediatric** at **Sex**. Pediatric samples are processed directly after the Stat samples. If you select pediatric in this field, you must place the corresponding sample in one of the positions P1 to P5, after confirmation in the **LOAD SAMPLES** menu.
- **Control**
  Requests that are recognized by the analyzer as controls. You can place controls in the positions C1 to C4 and in any position available for patient samples.
- **Calibrator**
  Calibrate tests, as described in the respective method sheets. You can place Calibrators in the positions S1 to S9 and in any position available for patient samples.
- **Blank**
  One position on the inner ring of the rotor is reserved for the reagent blank measurement. It is recommended to carry out a daily blank measurement for methods that require a reagent blank.

Test display

The screen shows a variable number of tests. The number depends on the programming made in the **TEST PROGRAMMING** menu. The maximum number of tests is 32. You can program the tests in the **TEST PARAMETERS** menu. In the **REAGENT POSITION** menu, you can define the test for the current reagent rotor.

* Optional

Keys

ARROW LEFT/RIGHT	Move inside an entry field from one position to the next.
ARROW UP/DOWN	Move the cursor to the next or previous field.
TAB	Switch between left and right fields.
ENTER	• Select or deselect a test from the test display. • Moves the cursor from one field to the next.
F1 WORK LIST	Print a list of all data in the request buffer.

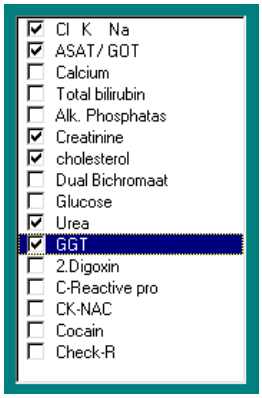
F2 STAT	Mark the sample request currently shown on the screen as an emergency sample.
F3 PROFILE	A window with all profiles for the current run mode appears. Select a profile from the list and press **ENTER**. All tests defined in that profile will be added to the current list of tests. You can program the profiles in the **PROFILES** menu.
F4 REPEAT MODE	Subsequent requests use the same set of test selections as default as the current one.
F5 PREV SAMPLE	Show the previous request in the request buffer.
F6 FORWARD SAMPLE	Show the next request in the request buffer.
SHIFT+F7 DELETE	Delete the request that is currently shown on the screen. The numbers of the following requests in the request buffer are changed accordingly.
ALT+F7 DELETE ALL	Delete all requests from the request buffer.
F8 NEW SAMPLE	Store the current request in the request buffer and clear the screen for a new request. If you selected the parameter **Sample no. autom. incr.** in the **SYSTEM PARAMETERS** menu, the sample number will increase automatically. If **F4 REPEAT MODE** is on, tests selected at previous patient will automatically be selected at current request.
F9 LOAD SAMPLES	Go to the **LOAD SAMPLES** menu (loading of the sample rotor).

4.1.2 Manually enter samples and test requests

Note

Always enter a sample number. The analyzer rejects requests without a sample number.

1. Enter the **Sample Number**.
2. Enter the **Sample Name** and the **Date of birth** if the laboratory is patient-oriented. These data are printed on each result report. You can change the date format in the **SYSTEM PARAMETERS** menu.
3. Enter the other parameters, if required.
   Or: Press **TAB** to go directly to the test selection area.
4. Select the required tests.
5. Press **F8** to store the request. An empty screen is shown for adding the next request.



The number of requests waiting for analysis in the request buffer is shown at the top of the screen (**Req./tray buffer:**). You can now select the **LOAD SAMPLES** menu with **F9**.

4.1.3 Read samples and tests with barcode reader

Preconditions

A barcode reader is the easiest, quickest and safest way to request samples and tests and to load samples. To use the barcode reader, following preconditions must be met:

- The primary tubes or the sample cups must have barcode labels.
- The requested tests must be marked on the barcode request chart that is provided by the manufacturer. The barcode label encodes the sample number, so a manual entry of the sample number is not necessary when you use a barcode reader.

Scan two barcode labels

In some cases, there are two barcode labels with identical patient data. One label is e.g. on the sample cup and one is on a separate form. If this is the case, proceed as follows:

1. Place the barcode reader on the sample label (form of labeled barcode).
2. Scan the code. The sample number is shown on the screen.
3. Place the barcode reader on the test that is selected on the barcode request chart.
4. Scan the corresponding test barcodes. The recorded test requests are highlighted. The checkbox is a marked.
5. Place the reader on the field **Quit** to record the next sample. Do not scan barcodes of the type Codabar.
6. Continue to record the data of the next patient.

4.1.4 Do test sequence in repeat mode

Use the repeat mode if you must run a number of samples with the same test selections.

1. Enter the historical data of a sample.
2. Press **TAB** to go to the shown tests.
3. Manually select a sequence of tests. Press **ENTER** to mark the tests.
4. Press **F4 REPEAT MODE**.
5. Press **F8** to clear the screen for the next request.

   If you selected the parameter **Sample no. autom. incr.** in the **SYSTEM PARAMETERS** menu, the sample number will increase automatically. If the first sample number was 001, the next number will be 002. If the last number is A-z-99, the next number will be B-a-00.
6. Press **F4** again to stop the repeat mode. A new request starts with a test list with no tests selected.

4.1.5 Request test profiles

Use the profiles to request repeatedly the same set of tests for a sample. You can define the profiles for the current run mode in the **SPECIAL FUNCTIONS** menu (**F5**). Program the profiles in the **PROFILES** menu (**F3**).

1. Enter the sample number.
2. Enter the historical data of the patient, if required.
3. Press **F3 PROFILE** to open a window with a list of profiles.
4. Select the desired profile.
   The test list for the current sample will show all the tests that belong to the selected profile.
5. Select additional tests or deselect tests, if necessary.
6. Press **F8** to store the current data. Clear the screen for the next request.
7. Repeat this procedure for each sample.

Note

Define the profiles separately for both run modes: Dual and Mono. A profile that you defined for the Mono mode is not available in the Dual mode.

Press ESC **to close the window without selecting a profile.**

You can also record a profile with the barcode reader.

Use profiles together with repeat mode

1. Press **F3 PROFILE** to open a window with a list of profiles.
2. Select the desired profile.
3. Press **F4**. Every new request that you created with **F8** will now have the tests for that profile.
4. Press **F4** again to stop the repeat mode.

4.1.6 Request a Stat-sample with barcode reader

To use the barcode reader, certain preconditions must be met. Refer to §1.1.3.

Press **F2** to change **the** sample status from **Normal** to **Stat**.

Or: Select **Stat** at the parameter **Sample Type**.

The analyzer will process the Stat-sample before all other samples.

Note

Place all Stat-samples to the assigned (Stat-) positions.

Change a stored sample or request into emergency sample

1. Select the required sample.
2. Press **F5 PREV SAMPLE** or **F6 FORWARD SAMPLE** to scroll through the list of stored samples and requests.
3. Press **F2 STAT** to change the status of the sample to **Stat**.

Select a test on barcode request chart

1. Scan the required test on the barcode request chart with the barcode scanner.
2. Record the next test.
3. If the scanned sample barcode is not coded with the barcode type Codabar, select the field **Quit** on the barcode request chart with the barcode reader. The screen for the recording of the next sample is cleared.

4.1.7 Request a pediatric sample

Children's samples are generally treated like normal samples. There are some differences:

- Select **Pediatric** at the parameter **Sex**.
- Select **Pediatric** at the parameter **Sample Type**.
- Pipette the pediatric samples in the specified sample cups. Use the supplied adapters. **Place the samples in the positions on the sample rotor marked with P1 to P5.**

Note

Pediatric samples have an increased danger of evaporation. To minimize this danger, the analyzer processes the pediatric samples with priority, directly after Stat samples.

4.1.8 Request controls, calibrators and blank determinations

You must regularly run the controls and calibrations. The frequency depends on the respective method, legislative regulations of each country and the organization of your laboratory.

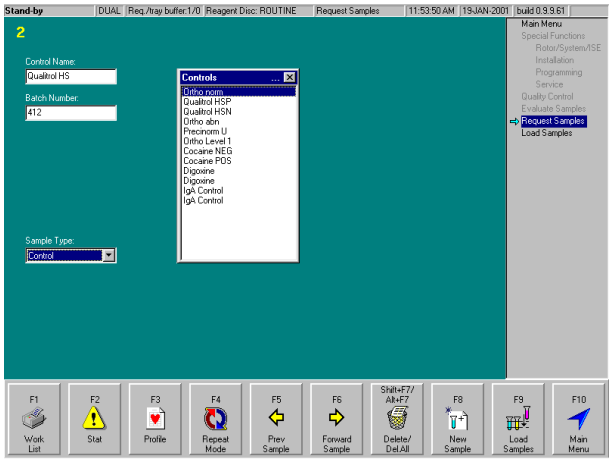
This also applies to the determination of reagent blank values. The necessary requests are recorded with the **REQUEST SAMPLES** menu.

Request the controls

1. Select the parameter **Sample Type.**
2. Select **Control** from the drop-down list.

   The parameters **Control Name**, **Batch Number** and **Sample Type** and a list of available controls are shown. These controls have been defined in the **CONTROLS** menu.
3. Select the required control.

   The parameter **Control Name** shows the name of the control. The **Batch Number** shows the lot number. On the right, a list is shown with all tests, which can be tested with this control. These tests have been defined in the **CONTROLS** menu.
4. Select the required test.
5. Press **F8** to clear the screen for a new control or sample request.



Request a test for calibration

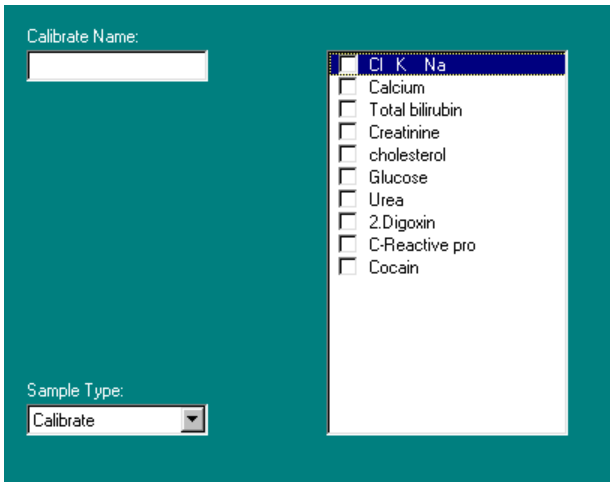
1. Select the parameter **Sample Type.**
2. Select **Calibrator** from the drop-down list.

   A list of available tests is shown. These tests require calibration according to their method sheet.
3. Select the required tests.
4. Press **F8** to store the selection. Clear the screen for the next request.

During the selection of the tests, no name is shown at **Calibrator Name**. The analyzer cannot assign the calibrators, until the request is completed.

Press **F5** to check which of the standards has been allocated to the individual tests.

Press **F6** to view the completed requests. The monitor shows **Calibrate** in the field **Sample Type**.



The name of the calibrator for this test is shown at **Calibrator Name** field. The calibrator is defined in the **TEST PROGRAMMING** menu.

Request a reagent for the blank determination

1. Select the parameter **Sample Type.**
2. Select **Blank** from the drop-down list.

   A list of available tests is shown. The list contains all tests that are previously defined in the **TEST PROGRAMMING** menu for a blank measurement
3. Select the required tests.
4. Press **F8** to transfer the request to the request buffer.

4.1.9 Delete a request

You can delete any request stored in the request buffer. A request can only be deleted if it is not loaded with **Confirm Load** in the **LOAD SAMPLES** menu.

1. Press **F5 PREVIOUS SAMPLE** or **F6 FORWARD SAMPLE**, to show the required request. The position of the actual sample in the request buffer is shown at the top left.
2. Press **SHIFT+F7** to delete the request from the request buffer.

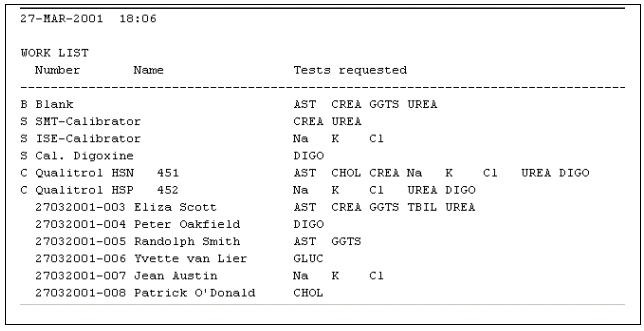
   When the request is deleted, all following request numbers are moved up by 1. The screen shows the new request with the current number. If you deleted the last request, the screen jumps to the first request.

4.1.10 Print a work list

Press **F1** to print the current work list. The work list shows these data:

- Lab. Name, Time and date
- Number of stored requests
- Patient name
- Assigned tests

The first column contains the sample type: Calibration (**S**), Reagent Blank Request (**B**), Stat sample (**E**), Pediatric sample (**P**) or Control (**C**).



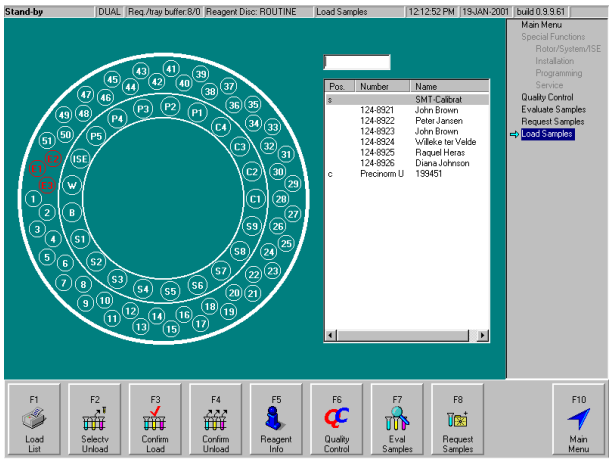
```
27-MAR-2001  18:06

WORK LIST
  Number       Name                Tests requested
-------------------------------------------------------------------------------
B Blank                            AST  CREA GGTS UREA
S SMT-Calibrator                   CREA UREA
S ISE-Calibrator                   Na   K    Cl
S Cal. Digoxine                    DIGO
C Qualitrol HSN   451              AST  CHOL CREA Na   K    Cl   UREA DIGO
C Qualitrol HSP   452              Na   K    Cl   UREA DIGO
  27032001-003 Eliza Scott         AST  CREA GGTS TBIL UREA
  27032001-004 Peter Oakfield      DIGO
  27032001-005 Randolph Smith      AST  GGTS
  27032001-006 Yvette van Lier     GLUC
  27032001-007 Jean Austin         Na   K    Cl
  27032001-008 Patrick O'Donald    CHOL
```

4.2 Load the sample rotor and start the tests

4.2.1 LOAD SAMPLES menu

The **LOAD SAMPLES** menu (**F9**) contains all functions for loading the sample rotor and starting the sample processing. You can place the programmed samples in any position on the outer two rings of the sample rotor. You can also load and start Stat samples, controls, standards and pediatric samples. As soon as a sample has been processed, the instrument indicates the new status of the sample.



You can place a new sample in the sample rotor, as soon as the processed sample has been removed. The analyzer will automatically analyze the new sample. You can also use the **LOAD SAMPLES** menu to check the volume of the loaded reagents, and to refill liquids if necessary.

Sample rotor parameters

The screen shows the sample rotor with all positions and their current processing status. The following display modes are possible for each position:

(1) – (51)	The position can be loaded.
1 – 51	The sample has been processed. You can remove the sample from the sample rotor.
(Darkened position)	The analyzer is currently processing the sample.
B	This position is used for the reagent blank value measurement. Always place the sample tube filled with distilled water or saline solution in this position.
S1 - S9	These positions are used for calibrator standards. If more positions are needed, you can use any position for normal samples (1-51).
P1 - P5	These positions are primarily used for pediatric samples. The analyzer processes these samples first, except for Stat-samples.
E1 - E3	These positions are used for Stat samples. These emergency samples are processed first.
C1 - C4	These positions are used for the controls. With the analyzer, you can use four controls for each batch. If more positions are needed, you can use any position for normal samples (1-51).
W	This position is used for the washing solution. For each analysis run, the washing position must contain a sample tube filled with a sufficient amount of washing solution. Recommendation: use a 10% Sputofluol solution as washing solution. After the last measurement of a batch, the analyzer automatically starts to pipette for cleaning the tubes and the valves. For cleaning, you must install HCl in the reagent rotor and a washing solution on the sample rotor. The cleaning consumes 6 times 400 µl HCl and 6 times 32 µl washing solution.

ISE When the optional ISE-unit is connected, this position is used for the ISE-activator (human serum).

Other parameters on right side of screen

Entry Field Enter the sample number of the requested patient sample. You can also record the barcode labels on the sample tubes with a barcode reader. The tube positions are determined by the sequence of entries.

Display Fields The analyzer shows all samples in the request buffer. The requests of special sample types are listed first (blank, calibrators, emergency, pediatric). Subsequently all "normal" samples and controls are listed in the order in which these were requested.

Keys

F1 LOAD LIST Print a load list when the loading is ready and the analysis run was started with **F3 CONFIRM LOAD**.

F2 SELECTIVE UNLOAD Unload specific samples that are ready, e.g. all controls or all normal samples. Then you can place a new sample on the emptied positions. If you press **F2**, a menu is shown. Here you can select, which type of samples must be unloaded.

F3 CONFIRM LOAD Start the analysis run after you have placed all samples in the sample rotor.

F4 CONFIRM UNLOAD When samples have been processed, you can remove them from the sample rotor. Confirm this with **F4**, before loading a new sample.

F5 REAGENT INFO Check the loaded reagents and their volumes in the **REAGENT INFO** menu. Do this check before each run to make sure that there is sufficient reagent for all requests.

F6 QUALITY CONTROL Check the results of the quality control.

F7 EVALUATE SAMPLES Immediately check all incoming results of the current analysis run and do validations, if necessary.

F8 REQUEST SAMPLES Go to the **REQUEST SAMPLES** menu.

F10 MAIN MENU Go back to the **MAIN MENU**.

4.2.2 Load the sample rotor

Place the samples on the rotor. Use the positions that are defined in the **LOAD SAMPLES** menu (**F9**).

The analyzer shows the requests for controls and normal samples on the right-hand side of the screen. The requests are shown in the sequence in which they were entered in the **REQUEST SAMPLES** menu. The special sample types are shown at the top of the list. You can identify these samples by the corresponding letter:

- B: Blank (1 position)
- S: Standard (9 positions)
- C: Control (4 positions)
- E: Emergency (3 positions)
- P: Pediatric (5 positions)

Load a blank measurement

Load a blank measurement before you load the calibrator.

1. Select the blank in the screen. The small **b** changes to a capital **B**.
2. Place the sample tube with distilled water or saline solution on position **B** of the inner rotor ring.
3. Select the calibrator. The small s changes to a capital **S1**. Place the sample tube with the calibrator on position **S1** of the inner rotor.

Load a patient sample

1. Select the patient or the sample number.
2. The analyzer assigns a position number to the selected sample. Place the sample in the relevant position of the sample rotor.
3. Load all other samples in the same way.

Note

The washing position (W) must contain a tube with washing solution (10% Sputofluol solution) for each analysis run.

The pediatric adapters and the small cups can be used for all types of samples, i.e. pediatric samples, standards, controls and normal patient samples. Do not place the small cups directly in the sample rotor without an adapter, because then the liquid sensor of the sample needle will not work.

You can also enter the sample number manually with the keyboard. A barcode reader can record the sample numbers directly from the barcode label on the sample tube.

Load sequence

When you place the samples in the sample rotor, you do not have to use the same sequence as the processing sequence that is defined in the **REQUEST SAMPLES** menu. Use the **ARROW UP/DOWN** keys to select the sample. Press **PAGE UP** or **PAGE DOWN** to scroll through the screen. Press **ENTER** to position the sample. The analyzer will process normal samples and controls in this order. Blanks, calibrators, Stat samples and pediatric samples, however, are always processed first.

4.2.3 Load samples with barcode reader

A barcode reader is the easiest, quickest and safest way to request samples and tests and to load samples. Refer to §1.1.3.

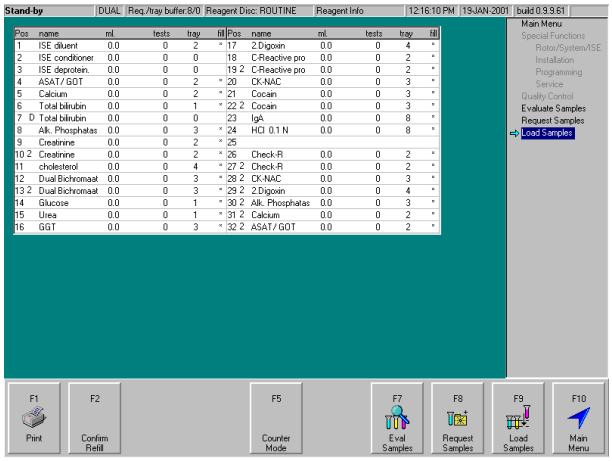
When you load samples with the barcode reader, you must scan the labels in the required processing order of the analyzer. Each scanned sample will be shown on the screen. The sample is labeled with the relevant position number.

Warning

To avoid mistakes, place the sample on the indicated position on the sample rotor as soon as you have scanned the sample.

4.2.4 REAGENTS INFO menu

The **REAGENTS INFO** menu (**F5**) shows the loaded reagents and their volumes. Use this menu before you start the analysis run.



Parameters

Pos.	The positions of the tests on the reagent rotor.
Name	The name of the reagent.
ml	The available reagent volumes.
Tests	The number of tests, which can still be processed with the available reagent.
Tray	The number of tests that is currently requested.
Fill	*: Refill the reagent.

Keys

F1 PRINT	Print a list with the reagent information.
F2 CONFIRM REFILL	Confirm that you have refilled the reagents.
ALT+F3 CLR.ALL COUNTS	In Counter mode: Delete the statistics and reset all counters to 0.
F5 COUNTER MODE	Switch between Counter mode and Normal mode.
F7 EVALUATE SAMPLES	Go to the **EVALUETE SAMPLES** menu to check all results and do validations, if necessary.
F8 REQUEST SAMPLES	Go to the **REQUEST SAMPLES** menu.
F9 LOAD SAMPLES	Go to the **LOAD SAMPLES** menu.
F10 MAIN MENU	Go to the **MAIN MENU**.

Check and refill reagents

1. Press **F5** to go to the **REAGENT INFO** menu.
2. Refill the reagents that are marked with an asterisk (*) in the **Fill** column.
3. Press **F2 CONFIRM REFILL**. The analyzer will assume that all the reagents have been refilled. The screen is updated.

Note

Check the loaded reagents and their volumes before you start the analysis run.

If you have already selected the REAGENT INFO menu (F5) before the start of the analyzer run, you can only go back to the LOAD SAMPLES menu (F9).

Insufficient reagent

The analyzer gives a warning, if the reagent volume becomes insufficient for a test during sample processing. **The test results, however, are not distorted or lost in any way**. The analyzer gives a message that you must refill the reagent and confirm this with **F2 CONFIRM REFILL**. The analyzer then repeats the test.

Note

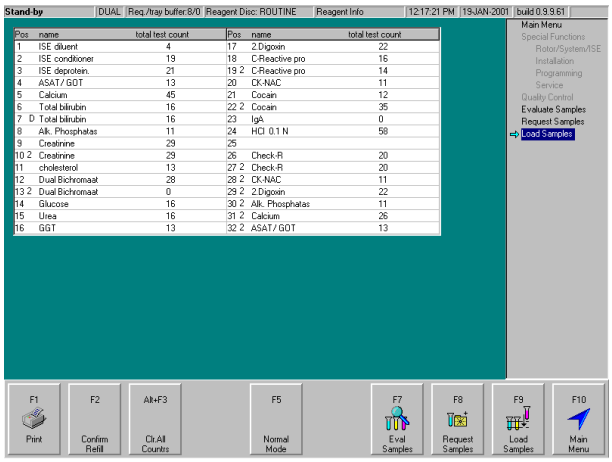
Check the loaded reagents and their volumes before you start the analysis run.

Counter mode and Normal mode

Press **F5 COUNTER MODE** to show the internal lab statistics. The Counter mode shows the total number of processed samples per method in both run modes. After changing from one mode to the other, also the test count indication changes.

Press **F5 NORMAL MODE** to return to the Normal mode.

Press **ALT+F3** to delete the statistics and to reset all counters to 0.



4.2.5 Start the analysis run

1. Place all samples, standards, controls, etc. in their correct position on the sample rotor.
2. Make sure there is a sufficient amount of reagents available for all requests.
3. Press **F3 CONFIRM LOAD** to start the analysis run. The positions, which are currently being processed, are not shown in the screen. As soon as a sample has been processed, the position is shown in inverted mode on the screen.

Note

Do not change to another menu except REAGENT INFO **before pressing** F3, **otherwise all position definitions for the sample rotor are lost.**

Start from standby-mode

If starting from the **Stand-by mode** (i.e. no other requests are currently being processed), the analyzer will first switch on the lamp and the vacuum pump, and rinse the cuvettes. Messages will inform you if any unusual incidents occur.

Print a load list

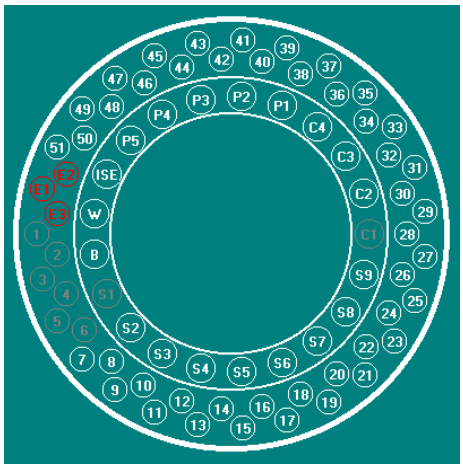
Press **F1 LOAD LIST** to obtain a printout of the loading list.

Unload the samples

1. Remove the sample tube from the rotor.
2. Press **F4 CONFIRM UNLOAD** to confirm that the sample was unloaded.
3. After unloading a sample, you can immediately load a new sample at that position on the sample rotor. If you press **F3 CONFIRM LOAD**, the new sample is integrated into the current run and will be processed.

Processing Stat and Pediatric Samples

Stat samples (**E1** – **E3**) and pediatric samples (**P1** – **P5**) are processed with priority. The same applies to reagent blank and calibrator measurements, as far as Stat Samples are concerned.



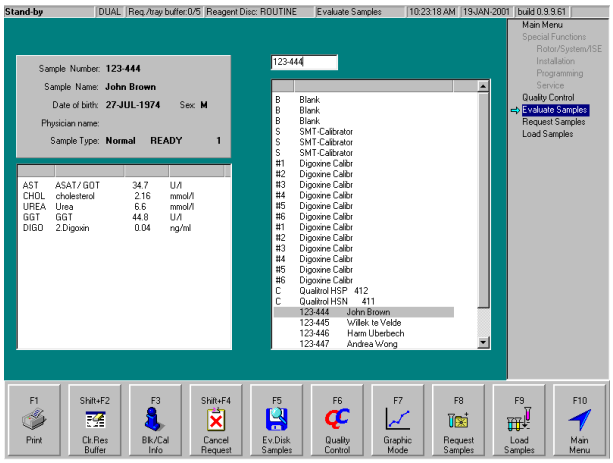
4.3 Checking and validating results

4.3.1 Evaluate Samples menu

The incoming results of each sample and test can be checked and, if necessary, validated in the **EVALUATE SAMPLES** menu.

A printout of results is generated automatically, if the parameter **Automatic Evaluation** was selected in the **SYSTEM PARAMETERS** menu. If you did not select this parameter, only results that have failed the test have to be manually validated. Subsequent samples will not be printed until the previous samples have all been validated.

Press **F7** in the **MAIN MENU** or in the **LOAD SAMPLES** menu to select the **EVALUATE SAMPLES** menu**.** Depending on the type of test, you can choose between a screen of the calculated absorbances in tabular or graphic form.



Parameters on left side of screen

Sample Number — The sample number as defined in the **REQUEST SAMPLES** menu.

Sample Name — The sample name as defined in the **REQUEST SAMPLES** menu.

Date of birth — The patient's date of birth is shown here, if it was entered in the **REQUEST SAMPLES** menu.

Physician name — The name of a physician in charge is shown here, if it was entered in the **REQUEST SAMPLES** menu.

Sample Type — The sample type (Normal, Pediatric, Control, etc).

Sex — The sex of the patient: **M** (male), **F (**female), or **P** (pediatric).

Status — The current processing status of the sample is shown in the status field directly behind **Sample Type**. The status field shows the position and the status of the samples on the sample rotor. The following status indications are possible:

- **In Process** — The sample or at least one of its allocated tests is currently being processed, i.e., the result of at least one test is pending.
- **Cancelled** — The sample was loaded, but the request was cancelled. The sample will not be processed and subsequently no results will be calculated.
- **Ready** — The sample has been processed. The results are available.
- **Loaded** — The sample is in the tray buffer, but processing has not yet started.
- **To Be Sent** — This message appears only if the analyzer is connected to a Laboratory Information System (LIS). The results can be sent to the host-computer.
- **Printed** — The result was printed.
- **Deleted** — The result was rejected.

Test Displays (Normal Mode)

All tests of a sample are shown together with their measurement results and their units. The screen shows up to 28 test results (without sample blanks) per patient in the normal mode. In the graphic mode, a maximum of 32 tests including sample blanks are shown.

If the word ***INFO*** is shown next to the corresponding test, you must press **F7** to validate the result. Press **F3** to accept the result or **F4** to reject the result, F5 to repeat the measurement or F6 to re-run the test with a specific rerun volume.

Parameters on right side of screen

Entry Field

When you enter a specific sample number, this sample is shown on the left side of the screen with the results. If the word ***INFO*** is shown instead of a result, you must validate the result manually.

Display Fields

All samples that have been or are currently being processed, are shown. Stat samples, controls, etc. are labeled with their respective letters. If you did not select the parameter **Automatic Evaluation** in the **SYSTEM PARAMETERS** menu, the samples, which require manual validation of at least one test, are listed first.

The left side shows the results of the currently selected sample.

Keys

F1 PRINT

Make a printout of the currently selected patient.

SHIFT+F2 CLEAR RESULT BUFFER

Delete all results that are currently shown. If you selected **Save before clear** in the **SYSTEM PARAMETERS** menu, the results will first be copied to hard disc.

F3 BLK/CAL. INFO

Go to the **BLANK/CALIBRATION INFORMATION** menu.

SHIFT+F4 CANCEL REQUEST

Cancel the currently requested samples any time during sample processing. The test is cancelled and a corresponding message is shown and printed out. The result is not calculated. Note that as the instrument is in fact already busy with this sample it might still pick up reagent for it.

F5 EV.DISK SAMPLES

Load the results that are stored on hard disk. A file list is shown. The file list shows the date and time of storage and the file size. Select a file with the arrow keys and press **ENTER**. When evaluating results from disk, only the final result is available, not the reaction curve.

F6 QUALITY CONTROL

Go to the **QUALITY CONTROL** menu.

F7 GRAPHIC MODE

Show the results of the sample that are shown on the left side of the screen, in graphic mode. Press **F7** again to go back to the normal mode.

F8 REQUEST SAMPLES

Go to the **REQUEST SAMPLES** menu.

F9 LOAD SAMPLES

Go to the **LOAD SAMPLES** menu. Further samples can be loaded here.

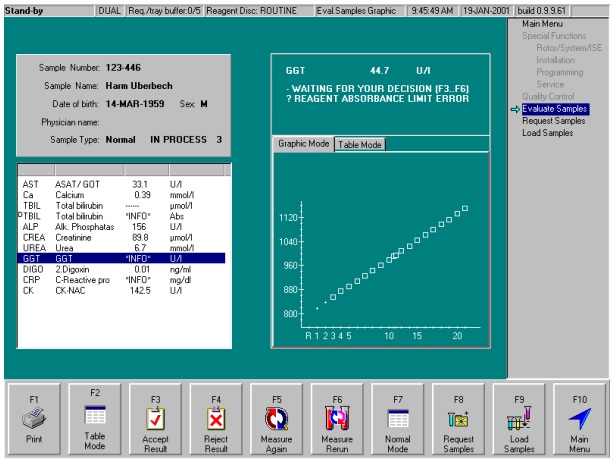
F10 MAIN MENU

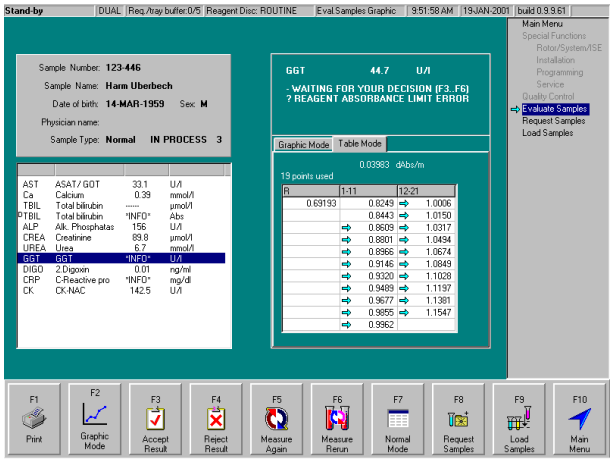
Go back to the **MAIN MENU**.

4.3.2 Test Displays: Graphic mode and Table mode

Press **F2 GRAPHIC/TABLE MODE** to show the results in detail. A separate prozone graphic and a prozone table can be called up if a prozone check was defined for a method in the **TEST PROGRAMMING** menu.

A maximum of 32 results including blanks are shown for each sample (left-hand side of screen). The current test and the respective unit are shown above the table or the graphic. The screen also shows the status of the test.





Parameters

Status

The status **Waiting For Your Decision** is shown if the word **INFO** is shown next to a result. Depending on the shown error message (e.g. **Insufficient Sample** or **Absorbance Limit Error**), the user may now either accept the result, reject the result, repeat the measurement or rerun the test with a specific rerun volume. Chapter 5 contains a list of possible error messages.

Graphic mode

The x axis of the graphic is the time axis. The x axis shows the kinetic measurement points in relation to the time function. 22 points (1 to 22) are available in the **Mono Mode**. 21 points (1 to 21) in the **Dual Mode**. The absorbance values are marked on the y axis.

If the cuvette (reagent plus sample) contains less than 220 µl during the measurement of a point, e.g. before the sample or reagent 2 is added, these measurement points will not be shown on screen. The measurement points in the coordinate system have following functions:

□ Used measurement point.

● Unused measurement point.

o The used slope point for the slope blank calculation or the used prozone point, depending on the display mode.

+ Measured reagent absorbance.

x Extrapolated value (reagent deviation), only used for sample start methods with falling kinetics or two point kinetics.

$R_{1,2}$ Reagent absorbance.

$E_{1,2}$ First or second measurement point in endpoint tests.

1 Measurement for the first wavelength.

2 Measurement for the second wavelength.

In bichromatic endpoint tests, point 2 is subtracted from point 1. In monochromatic endpoint tests, the average of point 1 and point 2 is calculated.

Table mode

Depending on the type of test method the following absorbance is shown:

- Calculated absorbance (endpoint)
- Delta absorbance (two point)
- Delta absorbance per minute (kinetic)

The number of measurements for kinetic or two point measurements depends on the mode:

- Mono mode: 22 measurements (1 – 22)
- Dual mode: 21 measurements

In endpoint tests (monochromatic or bichromatic), the measurement points are shown on the screen:

- Mono mode: after 11.5 minutes
- Dual mode: after 4.5 and 11.5 minutes

The measurement points marked with an arrow were used for calculation purposes by the analyzer.

The first column **R** shows the measured reagent absorbance for all methods (only if the volume of the first reagent is larger than 220 µl).

The second column (**1-11**) shows the points measured before the

second reagent was added.

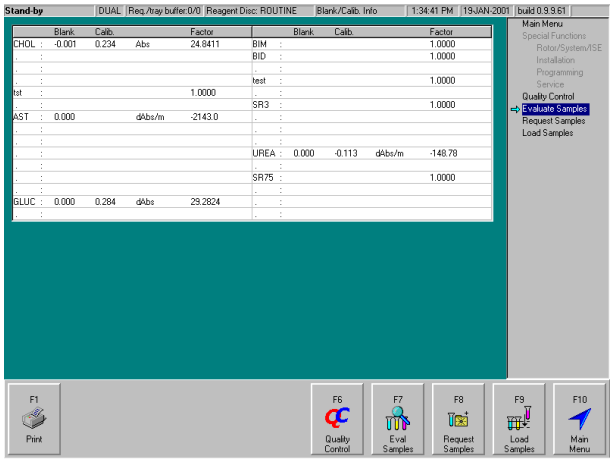
The third column shows the results of the tests run with the second reagent for the individual measurement points (below **12-21** or **E 11 .5 min.**). The shown absorbances are already corrected to meet the respective value of the total volume of the tests in the cuvette.

Keys

F1 PRINT	Print the current screen.
F2	Switch between graphic and table mode. Pressing **F7** or **ENTER** to return to the normal mode.
F3 ACCEPT RESULT	Transfer the tests (marked with ***INFO***) to the results printout, for a manual validation of test results. **WAITING FOR YOUR DECISION** is shown on the right-hand side on the screen. The result will only be transferred if this is enabled by the error that has caused the mark ***INFO***; i.e. **F3** is not available for serious errors such as **INSUFFICIENT SAMPLE**.
F4 REJECT RESULT	Reject the currently shown result. The rejected result is marked **REJECT**.
F5 MEASURE AGAIN	Repeat the test. The volumes that are used for the repeated measurement are identical with those that were originally used. The function is only available if the sample is *still* on the sample rotor (i.e. **F4** was *not* pressed in the **LOAD SAMPLES** menu).
F6 MEASURE RERUN	Automatically repeat the test. Unlike **F5** the defined volumes that are used here for the repeated test are the volumes that were defined in the field **Rerun Vol**. of the test parameters. The function is only available if the sample is *still* on the sample rotor (i.e. **F4** was *not* pressed in the **LOAD SAMPLES** menu).
SHIFT+F6 MEASURE ALL AGAIN	If a calibrator has been run in duplicate or in triplicate, the option **Measure All Again** appears. If selected, the instrument will measure this single standard again in duplicate or triplicate. Do not use this function if a calibration fails, but repeat the request of the entire calibration.
SHIFT+F2 TABLE/CURVE	If the test is a calibration, the calibration curve together with concentrations, measurement values and limit values are shown after pressing **SHIFT+F2**.
F7 or **ENTER**	Return to the normal mode.
F8 REQUEST SAMPLES	Go to the **REQUEST SAMPLES** menu.
F9 LOAD SAMPLES	Go to the **LOAD SAMPLES** menu.
F10 MAIN MENU	Go to the **MAIN MENU**.

Info-screen for blank/calibration

All programmed tests together with last blank measurement, last calibration result and the factor (from **TEST PROGRAMMING**) are shown.



Keys

F1 PRINT	Print a list of all shown results for blank measurements or calibrations.
F6 QUALITY CONTROL	Go to the **QUALITY CONTROL** menu.
F7 EVALUATE SAMPLES	Go to the **EVALUATE SAMPLES** menu.
F8 REQUEST SAMPLES	Go to the **REQUEST SAMPLES** menu.
F9 LOAD SAMPLES	Go to the **LOAD SAMPLES** menu.
F10 MAIN MENU	Go to the **MAIN MENU**.

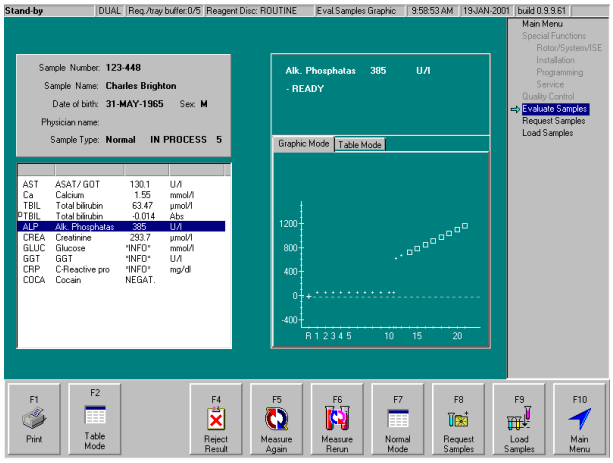
Results screen for kinetic test

The graphic mode shows the results of a kinetic test, run in the Dual Mode.

The analyzer shows 21 different points, marked on the x axis. To calculate the delta absorbance, the analyzer has used the last eight points (14 to 21). These points were measured after the second reagent was added. The first 13 points were only measured, but not used for calculation purposes.

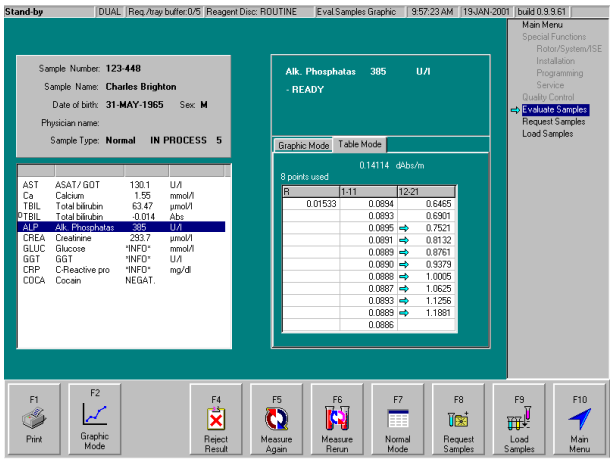
The arrow shown at the last point, measured before reagent 2 was added, shows the distance between this measurement point and the absorbance level of the substrate depletion (defined in the **TEST PROGRAMMING** menu), which is identified by the dotted line. Since none of the measurement points lies on or below this level, the substrate was never depleted during measurement.

As all measurement points lie inside the defined absorbance limits (also specified in the **TEST PROGRAMMING** menu), no error message is shown.



If you switch to the table mode with **F2**, the screen shows a table with the absorbances measured during the test. The result of the calculation is a delta absorbance per minute, shown at the top of the table.

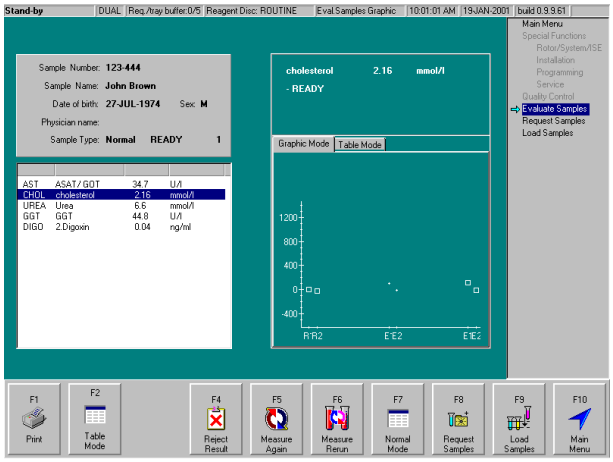
The table also shows that eight measurement points were used for the calculation. The measurement points used for calculation are the points 14 to 21, each of them marked with an arrow.



Results screen for a bichromatic endpoint test

In the graphic mode the result of a bichromatic endpoint test, run in the **Dual Mode**, is shown.

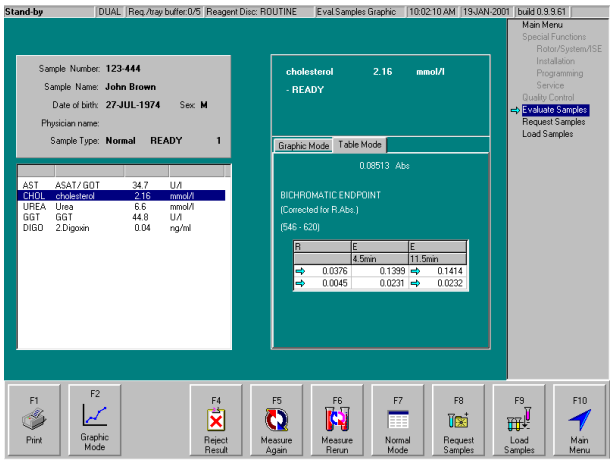
Six points are shown (marked on the x axis). To calculate the absorbance, the analyzer has used the two points measured after the first reagent was dispensed ($\mathbf{R_1}$ minus $\mathbf{R_2}$) and the two endpoints after an incubation time of 11.5 min. ($\mathbf{E_1}$ minus $\mathbf{E_2}$).



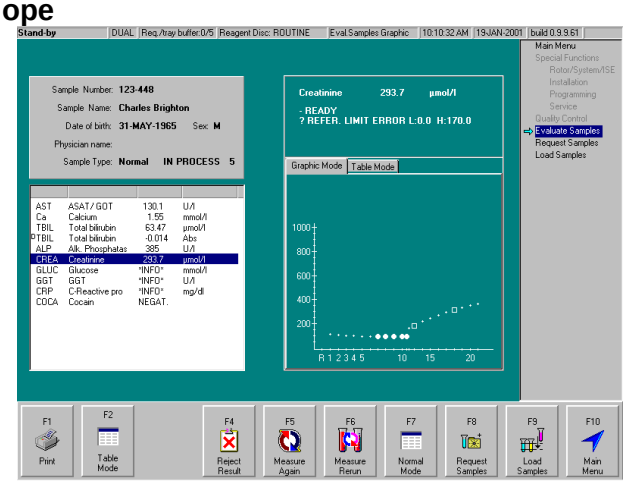
Press **F2** to go to the table mode. The example shows a table with the result of the calculation at the top (the absorbance value). The calculation is a bichromatic endpoint calculation and the result has already been corrected for the reagent absorbance.

The column **R** shows the results of the reagent absorbance measured for 546 and 620 nm.

The two remaining columns **E** show the results for the two endpoints, measured with the respective delay, at 546 and 620 nm. The arrows mark all points that are used for the calculation (depending on the programming made in the **TEST PROGRAMMING** menu).



Results screen for a two point test with blank slope



Sample Number: 123-448
Sample Name: Charles Brighton
Date of birth: 31-MAY-1965 Sex: M
Physician name:
Sample Type: Normal IN PROCESS 5

Creatinine 293.7 µmol/l
- READY
? REFER. LIMIT ERROR L:0.0 H:170.0

AST ASAT/GOT 130.1 U/l
Ca Calcium 1.55 mmol/l
TBIL Total bilirubin 63.47 µmol/l
DTBIL Total bilirubin -0.014 Abs
ALP Alk. Phosphatas 385 U/l
CREA Creatinine 293.7 µmol/l
GLUC Glucose *INFO* mmol/l
GGT GGT *INFO* U/l
CRP C-Reactive pro *INFO* mg/dl
COCA Cocain NEGAT.

Graphic Mode | Table Mode

-0.003 0.13118 dAbs

R	1-11	12-21
0.00000	0.1257	0.1757
	⇨ 0.1215	⇨ 0.1996
	0.1197	0.2320
	0.1164	0.2606
	0.1146	0.2850
	0.1130	0.3101
	⇨ 0.1112	⇨ 0.3308
	⇨ 0.1100	⇨ 0.3488
	⇨ 0.1095	⇨ 0.3651
	⇨ 0.1089	⇨ 0.3812
	⇨ 0.1085	

Main Menu
Special Functions
Rotor/System/ISE
Installation
Programming
Service
Quality Control
Evaluate Samples
Request Samples
Load Samples

F1 Print | F2 Graphic Mode | F4 Reject Result | F5 Measure Again | F6 Measure Rerun | F7 Normal Mode | F8 Request Samples | F9 Load Samples | F10 Main Menu

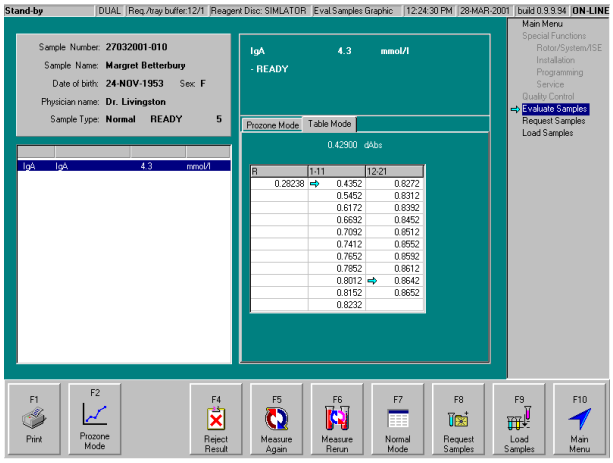
If you switch to the table mode with **F2**, the screen shows the absorbances in a table.

At the top of the table, the calculation results are shown by two delta absorbance values. The first value is the delta absorbance of the blank slope. The second value is the delta absorbance of the two-point test, not yet corrected by the blank slope. The column **R** states the measured reagent absorbance.

The column **1-11** shows the points measured for the slope blank. The points 7 to 11, marked with arrows, were used for the calculation. The column **12-21** shows the measurement points 12 to 21 that were used for calculating the test results. The points 13 and 18 were used by the analyzer.

Point 13 was subtracted from point 18 and resulted in the delta absorbance shown above.

Results screen for a two-point test with prozone check

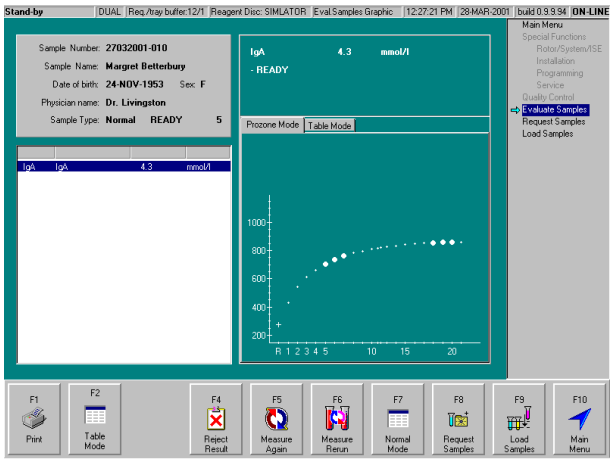


The prozone effect can occur in tests that are based on the principle of the antigen-antibody complex (agglutination). This effect often arises in patient samples with an extremely high antigen content. The surplus of antigen inverts the reaction direction (de-agglutination) and can cause incorrect or even "wrong" results.

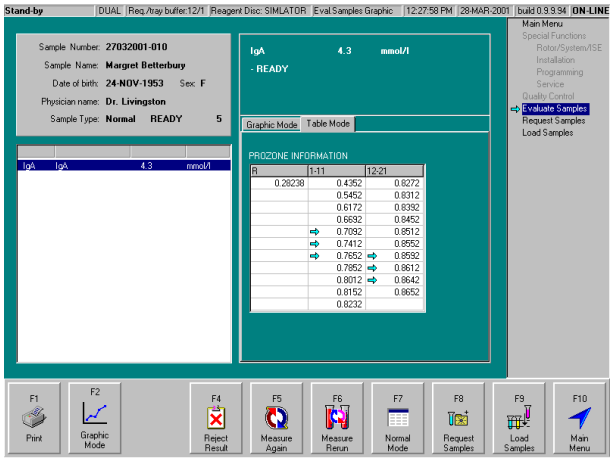
To avoid this effect, the analyzer offers a special check function for detecting prozone effects. You can define the prozone check in the **TEST PROGRAMMING** menu.

If the prozone check has been selected for a test, press **F2** again in the table mode to show the graphic of the prozone check.

Six points of the 21 measurement points were used for the calculation of the prozone check (2 x 3). These measurements are shown as circles. The **+** marks the measured reagent absorbance. Press **F2** again to show the table of the prozone check. Here the values of the graphic are shown as figures.



The analyzer calculates the slope ratio of the first three used points (5, 6, 7) and of the second three used points (18, 19, 20), respectively. The points used for the calculation are marked with arrows. The column **R** states the measured reagent absorbance.



4.3.3 Automatic Results Printout

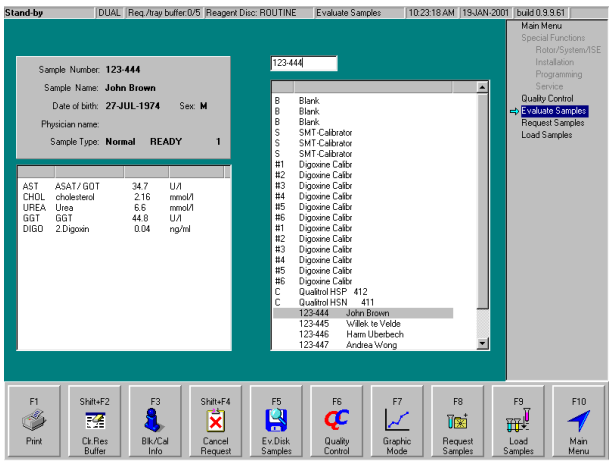
When the processing of a sample with all its requested tests is ready, the analyzer automatically prints out the results and sends the results to the Host through the LIS, if the analyzer is ON-LINE.

The printout includes the sample number, patient name, date of birth, sex, sample type, sample status and the tests that are done for that sample. The test results are shown with their respective units (mg/dl, mmol/l etc.).

If the parameter **Automatic Evaluation** in the **SYSTEM PARAMETERS** menu was not selected and one of the tests exceeds or falls below the limits that were defined in the test parameters (**TEST PARAMETERS** menu), the patient result will not be printed out, until a manual validation of the measuring results has been done.

The result will also not be printed, if error messages such as **Insufficient Sample** were shown.

4.3.4 Validation of a Result



In the **LOAD SAMPLES** menu or **MAIN MENU**, press **F7** to go to the **EVALUATE SAMPLES** menu. In this menu, you can check and, if necessary, validate results of a sample that is currently being processed.

You can check the test results of a sample, i.e. view the points in the graphic or compare the individual values of the absorbances. For this check, select the required sample with the arrow keys. Use **PAGE UP** or **PAGE DOWN** keys, if required**.** You can also enter the sample number in the entry field above the sample list to select the sample, or use the barcode reader.

The left screen shows all sample data, the position of the sample on the sample rotor and the status.

Press **F7** to go to the graphic mode. You can select one of the processed tests on the left with the cursor keys. A graphic of the corresponding test processing is shown.

When ***INFO*** is shown next to the test you must validate the results. This only applies if **Automatic Evaluation** in the **SYSTEM PARAMETERS** menu was not selected. The sample will not be released and the analyzer does not print it.

Sample information (number, name, etc.), test name and unit are shown above the table or the graphic. A message indicates why the test was not released. Due to this message (e.g. **Reagent Absorbance Limit Error**), you are required to make a decision (**Waiting For Your Decision**).

The graphic shows the result of a two-point test, run in the Dual Mode. Measurement points, which are used for the calculation, are shown as empty squares. Measurement points, which were not used for the calculation, on the other hand, are shown as filled circles

Press **F2** to show the values of the measurement points in tabular form. The individual absorbance values and the resulting delta absorbances are shown. The measurement points used for the delta absorbance are marked with arrows.

You can now accept the result with **F3**, reject it with **F4**, repeat the measurement with **F5** or run the test again with **F6**. If you select **F6**, the analyzer uses the sample and reagent volumes for the rerun, as they were entered when programming this method in the **TEST PARAMETERS** menu.

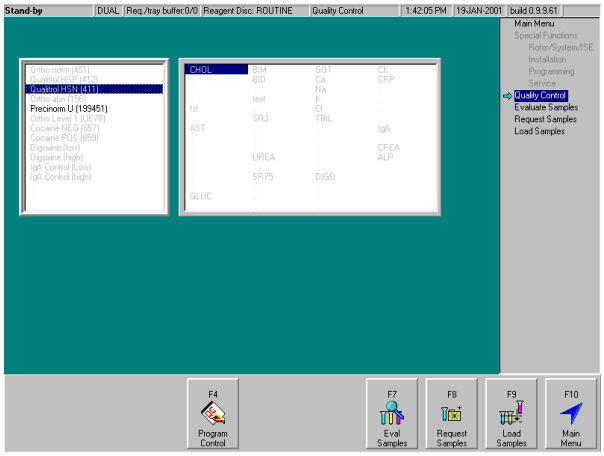
Extended Routine

5.1 Quality Control

The **QUALITY CONTROL** menu gives an overview of all measured control data. Any one of three controls previously assigned to the test in **PROGRAM CONTROL** can be selected to view the test in **Graphic Mode**, e.g. for stability and can be printed. This is not available for incomplete tests. The **PROGRAM CONTROL** can be selected from **QUALITY CONTROL** to change the assignment of controls and return to **QUALITY CONTROL**. This is available during measurement.

5.1.1 Start Quality Control

Select: **F10 MAIN MENU, F6 QUALITY CONTROL**



Parameters

Control fields (left-hand side of screen)	All controls in **PROGRAM CONTROL** (max. 15) are displayed in grey. All controls connected to a selected test are displayed in black.
Display fields (right-hand side of screen)	All programmed tests (max. 55) are displayed. All tests connected to the selected control are displayed in black. All controls connected to a selected test are shown in black on the left-hand side of the screen.

Function Keys

F1 PRINT/PRINT ALL	Prints the current display. The format can be either graphical of table.
F2 TABLE/GRAPHIC MODE	The analyzer moves from the **GRAPHIC** to the **TABLE** mode. Press **F2 GRAPHIC MODE** to return to the graphic mode. This function is available when in **TABLE MODE**.
F3 NXT/PRV.TEST	Selects the graphic representation of the next (**F3**) or the previous (**SHIFT+F3**) test of the current control.
F4 PROGRAM CONTROL	Changes the assignment of tests and controls in **PROGRAM CONTROL**.
F6 GRAPHIC/NORMAL MODE	When in **QUALITY CONTROL**, the results from selected control/test combination are displayed in graphic format. This function is available for valid control/test combinations. When in **GRAPHIC MODE**, **F6** returns to **QUALITY CONTROL**. The last 30 measurements are available.
F7 EVALUATE SAMPLES	Goes to the **EVALUATE SAMPLES** menu.
F8 REQUEST SAMPLES	Goes to the **REQUEST SAMPLES** menu.
F9 LOAD SAMPLES	Goes to the **LOAD SAMPLES** menu.
F10 MAIN MENU	Returns to **MAIN MENU**.

Keys

TAB	Move between the controls list and tests list.
ENTER	The same as **F6**. If an invalid control/test combination is selected, the message "Illegal combination" will be displayed.
CURSOR KEYS	Move within a list of controls or tests.

5.1.2 Graphic Representation of Quality Control

The analyzer displays a graphic representation of valid control/test combination measurements.

A maximum of 30 results per control and test are stored. If more than 30 tests are run, the earliest results are deleted (FIFO).

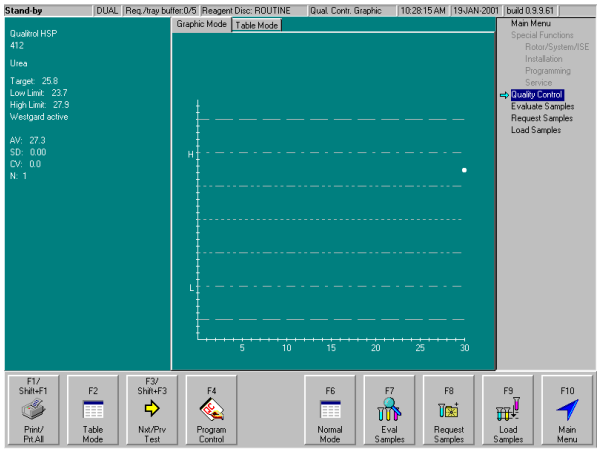
1. Select: From the **MAIN MENU, F6 QUALITY CONTROL** menu
2. Select: **CONTROL NAME**
3. Press **TAB**
4. Select: **Test**
5. Select: **F6 GRAPHIC MODE**.
6. Select: **F2 TABLE MODE** to view the table.
7. Select: **F2 GRAPHIC MODE** to view the graph.

Parameters visible in Graphic Mode (LHS)

The parameters shown to the left of the graph are as follows:

Control Name	Displays the name of the control.
Batch Number	Displays the reagent manufacturers batch number.
Test Name	Displays the name of the test assigned to this control.
Target	The reference value set in **PROGRAM CONTROL**.
Low Limit	The low limit as set in **PROGRAM CONTROL**.
High Limit	The high limit as set in **PROGRAM CONTROL**.
Westgard	Displays the status of Westgard option.
AV	Displays the mean value of all measured values.
SD	Displays the standard deviation of the measured values.
CV	Displays the coefficient of variation of the measured values as %.
N	Displays the number of control measurements.

Graphic Displays (RHS)



Points on the graph

Each point represents one control measurement with the corresponding test. The quality of the test can be monitored from the spread of the points.

The display of the points depends on the mode (**DUAL/MONO MODE**) that the control was run and whether the measurements meet the evaluation rules (Westgard rules):

• = measurement **DUAL MODE**

o = measurement **MONO MODE**

X = does not meet the Westgard rules.

H

The line **H** indicates the set **HIGH** limit

L

The line **L** indicates the set **LOW** limit

Arrow

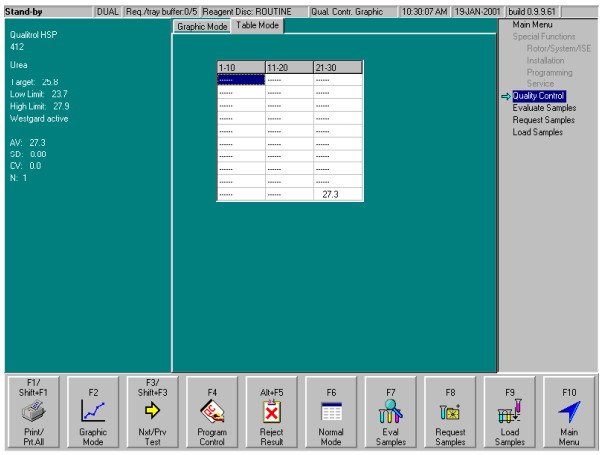
An arrow (pointing up or down) indicates that a result is outside the range of the graphic display. The result must be checked in **TABLE MODE** and marked **Reject** if necessary.

R

An R at the top or lower edge of the display indicates that the operator in **TABLE MODE** has rejected the result.

Table Mode.

The columns display the results of the last 30 control measurements. To reject a control result, select the result using the cursor keys or the mouse and select **ALT+F5 REJECT RESULT**.



5.2 Program Controls

The controls are programmed before the analyzer is put into operation for the first time. Assign the tests after method definition and reagent positioning. You can change method assignments and program new controls later. Only the name and batch number of the control has to be entered. A total of 15 controls can be set with a maximum of 3 controls per test.

5.2.1 Start PROGRAM CONTROLS

1. From the **MAIN MENU**, select: **F5 SPECIAL FUNCTIONS**, **F3 PROGRAM**
2. Select **CONTROLS**.

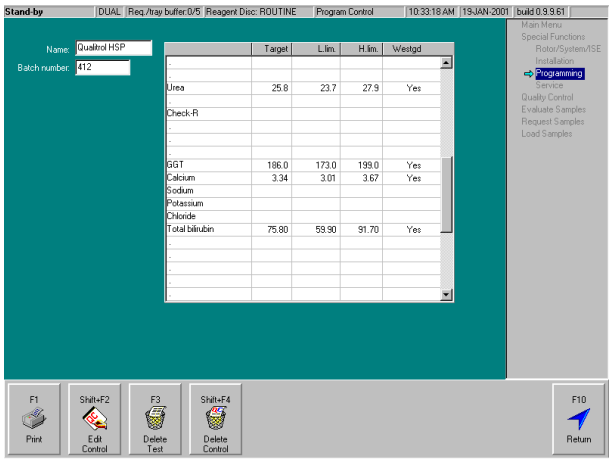
5.2.2 PROGRAM CONTROL Parameters

Name — The name of the control as provided on the insert sheet. Enter the name here, if you are programming a new control.

Batch number — The batch number as provided in the insert sheet. Enter the batch number here, if you are programming a new control.

5.2.3 Program Controls Display Fields

The analyzer displays the programmed tests that can be assigned to the **CONTROL NAME** displayed on the left. You can scroll using the **PAGE UP** and **PAGE DOWN** keys or the **SCROLLBAR**.



All values set to the test are displayed: the **target value**, the **low limit,** the **high limit** and information whether **Westgard rules** apply to control results. To enter or change values, do as follows.

1. Select a test from the list that will use the selected control.
2. Place the curser over the test.
3. Press the **ENTER** key.
4. The values from the **CONTROL PROGRAMMING** screen are displayed.

Note: With cut-off tests, only the set value is displayed for the positive or negative result.

5. Enter the values for **Target, Low Limit, High Limit, Westgard Active**.
6. Press **F10 RETURN** to return to the **PROGRAM CONTROLS** screen.

The same screen can be activated from within the **QUALITY CONTROL** menu by pressing **F4 PROGRAM CONTROL**. However, this should only be done if a name and batch number have already been assigned to the control.

Function Keys

F1 PRINT — Print out a list of all tests assigned to the current control.

SHIFT+F2 EDIT CONTROL — Place the cursor in the field NAME. Select Edit Control. You may now enter a new name and/or batch number for that control. All test assignments to the current control are deleted.

F3 DELETE TEST — Deletes the assignment of the test to the current control.

SHIFT+F4 DELETE CONTROL — To delete the current control. There is no confirmation and all the related quality control test results are also deleted.

F10 RETURN Goes back one screen to either **QUALITY CONTROL**, or **PROGRAMMING**. All changes made are saved.

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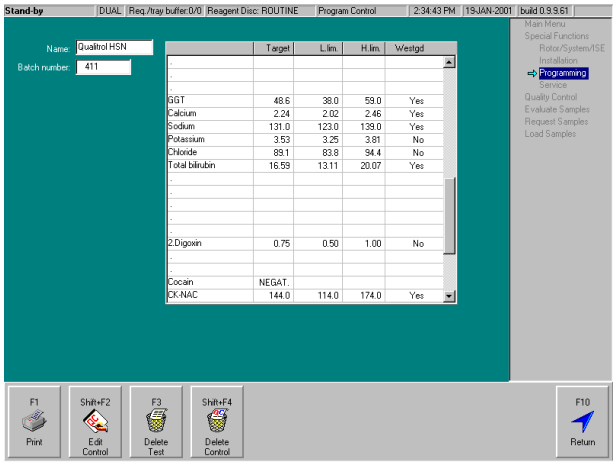
5.2.4 To Enter a control and assign the control to a number of tests



1. From the **MAIN MENU** select **F5 SPECIAL FUNCTIONS, F3 PROGRAM**
2. Select **CONTROLS**.
3. Press **TAB** or **ENTER** to move to the list of controls.
4. Select the next free entry.
5. Press **ENTER** or double click to call up the screen for programming a new control.

The cursor is in the field **Name**.

6. Type the name of the control and confirm with **ENTER**.
7. Type the batch number of the control in the **Batch Number** field. The batch number can be found on the insert sheet of the control.
8. Press **ENTER** to move to the test selection list.
9. Select the test to be assigned using the **CURSOR** keys or the mouse.
10. Press **ENTER** or double-click on it to assign it to the control.
11. Enter the **Target value**, the **Low Limit** and **High Limit**, and select **Westgard active**, if necessary.
12. Press **F10 RETURN** to return to the test list.
13. To assign other tests to the control, place the cursor on the test name and press **ENTER** or double click. Repeat these steps.

Note:

Target values and limits must be entered according to the values given on the insert sheet. The right-hand side of the screen should now look like the display shown in our example.

5.2.5 Assign a control to a cut-off test

1. Select the **Cut-off** test and press **ENTER**.
2. Choose between positive and negative values:
   1. Select **Positive** if the result of the control has to be positive. A negative test result is marked with a flag.
   2. Select **Negative** if the result of the control has to be negative. A positive result is marked with a flag.
3. Place the cursor either on positive or negative.
4. Press **F10 RETURN** to return to the test list. The selected function is displayed next to the test.

5.2.6 Delete the assignment between a quality control and a test

1. Select the test from the test list of the Program Control screen.
2. Press **F3 DELETE TEST**.

5.2.7 To change or delete a control (e.g. when the batch/lot number has changed)

1. From the **MAIN MENU**, select **F6 QUALITY CONTROL**, **F4 PROGRAM CONTROL**.
2. Select **SHIFT+F2 EDIT CONTROL** to edit the displayed control, or **SHIFT+F4 DELETE CONTROL** to delete it **without confirmation**.

Caution

The existing results of the quality control are lost if the control is changed or deleted.

5.2.8 Westgard Rules

The Westgard rules used on the analyzer are valid only for single controls. They evaluate the quality controls according to the following rules:

- If 1 result of the control is outside 3 standard deviations, the Westgard rules are broken.
- If the last 2 control results exceed 2 standard deviations in the same direction (+ or –), the Westgard rules are broken.
- If the last 4 control results exceed 1 standard deviation in the same direction (+ or –), the Westgard rules are broken.
- If the last 10 control results are all located either on the '+' or the '–' side to the mean, the Westgard rules are broken.
- If one test result of the control is within 2 standard deviations, the Westgard rules are not broken.

The Westgard rules are not violated in all other cases.

5.3 Programming Calibrators

Calibrators must be programmed before you define the test parameters for the various tests. You can change the parameters for a calibrator or add new calibrators later. A total of 50 calibrators can be set.

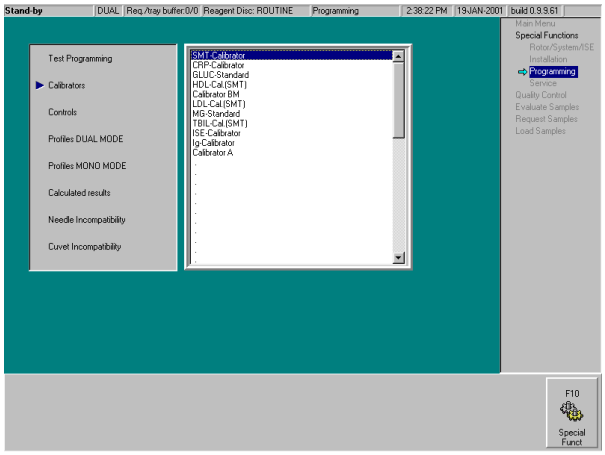
The analyzer supports 3 calibration methods:

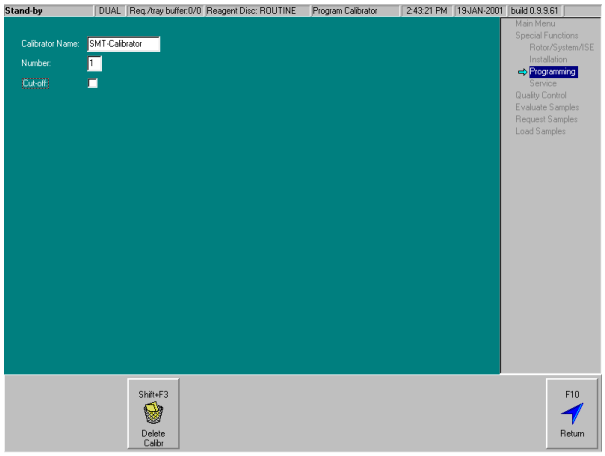
- linear calibration with 1 standard, where a concentration of 0 shows no reaction
- linear calibration with 2 standards
- non-linear calibration with 3 to 9 standards

All these methods will give quantitative results.
Where a qualitative result is required (either positive or negative) cut-off calibration must be used. With a cut-off calibration you can also define a “close to cut-off” or “grey”-area.

5.3.1 Program a Calibrator

1. From the **MAIN MENU**, select **F5 SPECIAL FUNCTIONS, F3 PROGRAM** and select **CALIBRATORS** from the menu. A list of programmed calibrators appears.
2. Press **TAB** or **ENTER** to move the cursor to the list of calibrators.
3. Select the name of a calibrator to be modified or an empty position for defining a new calibrator using the cursor keys or the mouse.
4. Press **ENTER** or double click on the selected position to call up the **PROGRAM CALIBRATOR** screen.





Parameters

Calibrator Name The name of the Calibrator.

Number The number of standards (1-9) for this calibrator.

Cut-off When the number of standards is 1, the cut-off option appears. When you select the cut-off option the test result will be in qualitative form. To select cut-off check the check box.

Function Keys

SHIFT+F3 DELETE CALIBR Delete the current calibrator from the list of calibrators.

F10 RETURN Return to the PROGRAMMING menu.

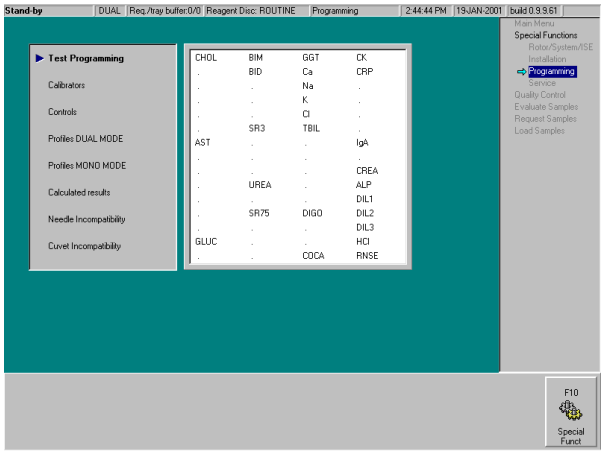
5.4 Programming Test Parameters

All entries for each method are recorded in the **TEST PROGRAMMING** menu. The analyzer can give correct results only if the correct test parameters from the method sheets are entered. The analyzer is delivered with a set of common parameters. Please contact your reagent supplier to confirm that these parameters are applicable for their reagents. To modify a test or to add a new test, use the **TEST PROGRAMMING** menu and the parameters given in the method sheets.

The **PROGRAM TEST** screen consists of three pages. Page 1 contains the global values that are independent of the run-mode. These values must be set to the values given in the respective method sheet. Page 2 is for values that are required for **Dual Mode**. Page 3 is for values that are required for single reagent use or **Mono Mode**. Complete the pages as required for either dual or mono mode applications.

Parameters values are saved to hard disk. Changes to the values will overwrite existing values without confirmation. The retrieval of the “old “ parameters values is not possible unless a back up of the test parameters has been made.

5.4.1 TEST PROGRAMMING Parameters



Start Test Programming

1. From the **MAIN MENU**, select **F5 SPECIAL FUNCTIONS**, **F3 PROGRAM**.
2. Select **TEST PROGRAMMING**

All programmed tests are displayed on the right-hand side of the screen. Additional tests may be entered in free positions. A maximum of 55 tests can be programmed.

Add a new test

3. Press **TAB** or **ENTER** to go to the test list.
4. Move the cursor to a free field
5. Press **ENTER** or double click on the appropriate entry.

The first page of the **PROGRAM TEST** screen is shown.

6. Enter the test parameters according to the respective method sheet here.
7. Select **F10 Return** to return to **Test Programming** menu. Repeat these steps to program additional tests

Note

Enter the parameters exactly as in the method sheets.

Modify an existing test

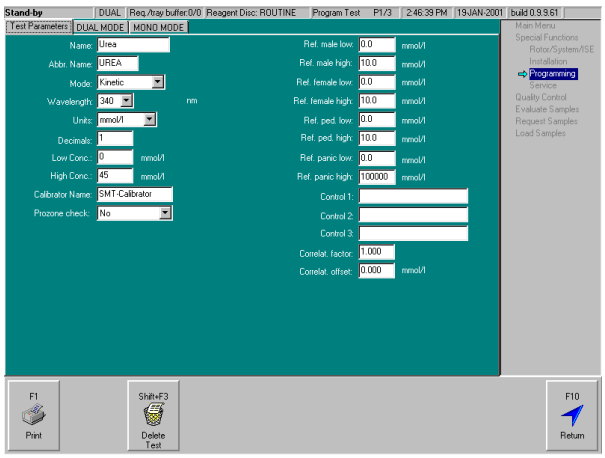
1. Press **TAB** or **ENTER** to go to the test list.
2. Move the cursor to the corresponding field
3. Press **ENTER** or double-click on that field.

The first page of the **PROGRAM TEST** screen (**TEST PARAMETERS**) is shown with the values set for the selected test.

4. Make the necessary changes to the parameters.
5. Select **F10 RETURN** to return to **TEST PROGRAMMING** menu
6. Select **F10 SPECIAL FUNCTIONS** to return to the **SPECIAL FUNCTIONS** menu

5.4.2 Program Test Parameters

The programming of twopoint and endpoint tests is for most parameters identical to kinetic tests. However, depending on the selected measurement mode (Kinetic, two-point, endpoint), some fields are not applicable and are therefore not displayed. Differences are described in the following section.



Name — The name of the test. You must enter text to this field. If no name is entered, the test parameters will not be stored.

Abbr. Name — The abbreviated form of the test name. You must enter text to this field. If no name is entered, the test parameters will not be stored.

Mode — Select the measurement mode from the drop down list. **Kinetic, Endpoint, Twopoint**.

Wavelengths — Select the wavelength as given in the method sheet from the drop down list. The dropdown list contains all available wavelengths. For a monochromatic endpoint measurement, both wavelengths must be identical.

Units — Select the desired units from the drop down list. All test results will be displayed and printed using this unit.

Decimals — Select the number of decimal places for patient or control data used in display and printout. If the test has not been calibrated or if the factor is exactly 1, the analyzer automatically selects 3 decimal places. In this case the unit is selected in accordance with the selected test method: absorption for endpoint tests, delta absorption for twopoint tests, delta absorption per minute for kinetic tests.

Low Conc. — The value for the low limit of the measuring range from the method sheet. If the value falls below of the set limit, an error message is given.

High Conc. — The value for the high limit of the measuring range from the method sheet. If the set limit is exceeded, an error message is given or will retest using a lower sample volume (Depending if **Automatic Rerun** is selected in **SYSTEM PARAMETERS** menu)

Calibrator Name — If the test has to be calibrated, a calibrator must be selected from the list of set calibrators. Press **ENTER** and a drop down list with all calibrators appear. Press **ENTER** again and select the appropriate calibrator using the cursor keys or the mouse. After a calibrator has been selected the **PROGRAM CALIBRATOR** screen appears (Refer to chapter 1.5) .

Prozone check — The prozone effect can occur in tests based on the principle of the formation of an antigen-antibody complex (agglutination), e.g. in Ig tests. The effect often occurs in patient samples with a very high antigen content. The surplus of antigen inverts the reaction direction (de-agglutination) and causes incorrect measurement values for the sample. To avoid this, the analyzer offers a prozone check function.

Press **ENTER** and a drop down list with all prozone options appears:

- **No**,
- **Min. δAbs ratio**,
- **Min. Abs ratio**,
- **Max. δAbs ratio**
- **Max. Abs ratio**.

If **Min. δAbs ratio** or **Max. δAbs ratio (δAbs = Delta Absorbance**) is selected, the analyzer calculates the respective delta absorbances of 2 x 3 measurement points at two different points in time (prozone points 1 and 2). Both delta absorbance values are divided and then multiplied with the factor 100 ((delta absorbance proz. point 1/delta absorbance proz. point 2) x 100). The result percentage is called DELTA ABSORBANCE RATIO. If **Min. δAbs** ratio is selected and the result falls *below* the set minimum rate (e.g. 80%) or if the **Max. δAbs** ratio is selected and the result *exceeds* the set maximum ratio, the analyzer detects a prozone error and marks the corresponding result with a prozone flag.

If the **Min. Abs** ratio or **Max. Abs** ratio is selected, the analyzer calculates the respective absorbance of 2 x 1 measurement points at two different points in time (prozone points 1 and 2). Again both values are divided and then multiplied with 100. The further calculation operations are identical with those of the delta *absorbance* ratio. If a prozone error is detected by the system, the corresponding result will be marked with a flag.

minimum ratio
maximum ratio

The percentage minimum or maximum ratio – depending on the selection in **Prozone check** – of the two absorbance values (or delta absorbances) calculated by the system. If this value is exceeded, the analyzer detects a prozone error and marks the corresponding result with a prozone flag. The default setting is 80%.

The other prozone parameters are entered on pages 2 (DUAL MODE) and 3 (MONO MODE) and are described there.

Ref. male low

The low limit of the reference range for male samples. If a measured value is below this limit, the analyzer flags the result.

Ref. male high

The high limit of the reference range for male samples. If a measured value is above this limit, the analyzer flags the result.

Ref. female low

The low limit of the reference range for female samples. If a measured value is below this limit, the analyzer flags the result.

Ref. female high

The high limit of the reference range for female samples. If a measured value is above this limit, the analyzer flags the result.

Ref. ped. low

The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.

Ref. ped. high

The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result.

Ref. panic low

The low panic limit of the reference ranges for all types of samples. If a measured value is below this limit, the analyzer flags the result on the printout if the report set-up is enabled.

Ref. panic high

The high panic limit of the reference ranges for all types of samples. If a measured value is above this limit, the analyzer flags the result on the print-out if the report set-up is enabled.

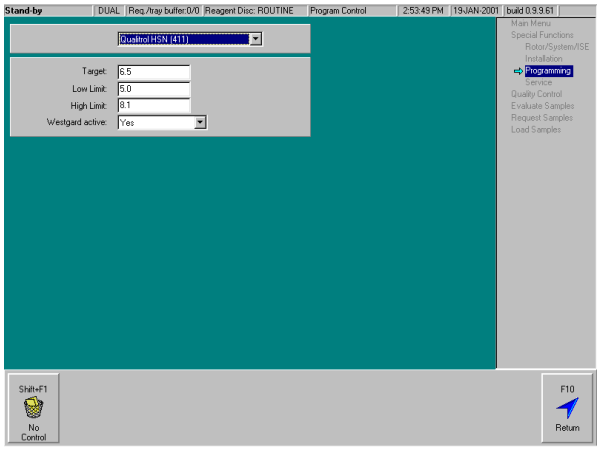
Note

The respective Ref. high **value must always be greater than the corresponding** Ref. low **value! If a low and a high limit are identical the analyzer will not check these limits and will not flag the results.**

Control 1
Control 2
Control 3

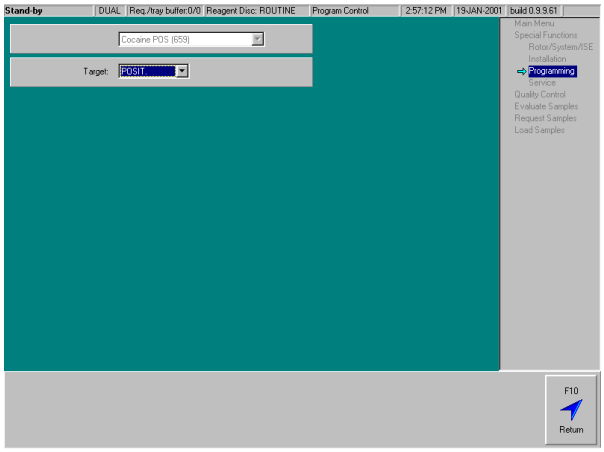
A maximum of three controls can be assigned to one test. Press **ENTER** or double-click in one of the fields, the analyzer displays the **PROGRAM CONTROL** screen.

1. Press **ENTER** to open the drop down list.
2. Select one control and press **ENTER** again.
3. Enter the **Target value** and the **Low** and **High Limit**. The respective values are given in the insert sheet for the control. Select **Yes** from the **Westgard active** drop down list to control the evaluation to Westgard rules.
4. Confirm your entry and return to **THE TEST PARAMETERS** screen by pressing **F10 RETURN**. Additional controls can be programmed as described above. To delete a selected control, press **SHIFT+F1 NO CONTROL** in the **PROGRAM CONTROL** screen.



For test with qualitative evaluation method (*cut-off*), the screen displayed below is shown.

1. Press **ENTER** in the field **Target**.
2. Select either **Negative** or **Positive** from the drop down list.
3. Confirm your selection and return to the previous menu with F10 **RETURN**
4. Set remaining controls if necessary.



Correlat. factor

The correlation factor is a calculation factor used internally by the system. The analyzer multiplies the result of the measurement with the value entered in this field. The setting 1.000 is the default value for all methods with a quantitative evaluation. No correlation factor is available if a qualitative evaluation (*cut-off*) was selected for the corresponding test.

Correlat. offset

The value entered in this field is a calculation value used by the system. The analyzer adds the correlation offset as a constant value to the result of the multiplication of measured result and correlation factor:

(measuring result x correlation factor) + correlation offset = final result

The default setting for all methods is 0.000. The correlation offset is not available for cut-off tests.

Note

The difference (Bias) between individual methods on different analyzers can be balanced out by means of the correlation factor and correlation offset.

Screen Page 2 (DUAL MODE) and Screen Page 3 (MONO MODE)

The functions of the individual fields for **Dual Mode** and **Mono Mode** are identical. Only the fields for the second reagent and the field Substrate depletion are missing on Screen 3.

Name

The test name as set on Screen Page 1, Test Parameters

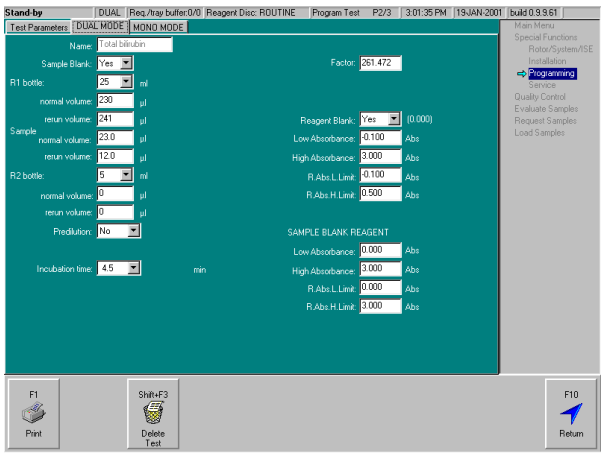
Sample Blank

Select whether to measure a sample blank in a separate cuvette for the corresponding test. Obtain the information from the test method sheet as to if a sample blank measurement is needed.

Press **ENTER** in this field, select **Yes** or **No** from the drop down list and press **ENTER** again to confirm. If you select **Yes**, screen pages 2 (this page) and 3 (**Mono Mode**) show fields for parameters regarding the sample blank. For a description of these parameters see later in this chapter.

The sample blank reagent (or *dummy reagent*) is treated as a normal reagent regarding placement on the reagent rotor and incompatibilities. The dummy reagent is distinguished from the normal reagent by superscripted D in front of the reagent name:

TBIL = normal reagent for Bilirubine
^{D}TBIL = dummy reagent for Bilirubine



R1 bottle

Press **ENTER** to show a drop down list of the available bottle sizes. Select one size for reagent 1 bottle (5, 25 or 50 ml).

Normal Volume

Enter a reagent volume between 220 µl (or with R2 110 µl) and 399 µl. Enter the volume in steps of 1 µl. The total of the normal reagent volume (R1 and R2) and normal sample volume may not be less than the cuvette's minimum volume (220 µl), otherwise the entry in this field is automatically increased to a total volume of 220 µl. The maximum volume is 400 µl.

Re-run Volume

The reagent volume for a rerun. Enter a reagent volume between 220 µl (or with R2 110 µl) and 399 µl. The analyzer needs this value to perform an automatic rerun, if necessary. Enter the volume in steps of 1 µl. The total of the normal reagent volume (R1 and R2) and normal sample volume may not be less than the cuvette's minimum volume (220 µl), otherwise the entry in this field is automatically increased to a total volume of 220 µl. The maximum volume is 400 µl.

Sample normal volume

Enter the normal sample volume in 0.1 µl steps between 1 and 30 µl. It is recommended to not enter a sample volume less than 3 µl.

Sample rerun volume

Enter the sample rerun volume in 0.1 µl steps between 1 and 30 µl. The analyzer needs this value to perform an automatic rerun, if necessary. It is recommended to not enter a sample rerun volume less than 2 µl. The analyzer corrects the rerun results according to the reduced sample ratio.

R2 bottle

As for R1, a choice can be made between 3 bottle sizes (5, 25 and 50 ml).

Note

A bottle size must always be selected. If a reagent is not used, select a bottle size and enter 0 µl for the normal and the rerun volume.

normal volume

Enter a volume between 0 and 180 µl.

rerun volume

Enter a rerun volume between 0 and 180 µl

Predilution

The sample can be pre-diluted in the **Dual Mode** only. Press **ENTER** in this field and select a pre-dilution ratio (1:5, 1:10, 1:20, 1:30, 1:40, 1:50 or **NO** for no pre-dilution) from the drop down list.

E.g. a dilution ratio of 1:5 means 1 part of the sample diluted with 4 parts of diluent that results in 5 parts of solution.. Confirm with **ENTER**. If you selected a ratio, a field appears, from which you have to select the diluent. Press **ENTER** to open the list of diluents (**DIL 1, DIL 2, DIL 3**), select one diluent from the list and press **ENTER** again to confirm your selection.

Note

The selected diluent must be positioned in the REAGENT POSITION DUAL MODE **menu. A bottle with the diluent has to be placed in the corresponding position on the reagent rotor.**

When predilution is used, the instrument uses an extra cycle for preparation of the diluted sample. In the first cuvette diluent is dispensed and sample is added and mixed. In a second cuvette the reagent is dispensed. The sample needle will pick up the diluted sample from the first cuvette and add it to the reagent in the second cuvette.

The sample volume set in the test parameters refers to the volume of the diluted sample. The instrument itself determines how much concentrated sample and diluent will be picked up.

Delay, min.time

Kinetic Measurement Mode. Press **ENTER** to open a drop down list with incubation times (values in seconds).

If only reagent 1 is used, the incubation time is the time interval between the addition of the sample and the beginning of the first measurement.

If reagent 2 is used, the incubation time is the time interval between the addition of the *last* reagent and the beginning of the first measurement. Select a minimum measuring time from the second drop down list.

If no linearity error has been detected on the first four measurement points after the incubation (delay) time and during the minimum measuring time, the analyzer uses all the measurement points that were measured during the minimum measuring time. E.g.. 50 seconds is entered as delay and 186 seconds for the minimum time, the analyzer measures the first point after 50 secondsand the last point 186 seconds *later*.

If, the instrument detects a linearity error after the first 4 measurement points, the analyzer uses as many points as possible for the calculation (even *after* the minimum time). In both cases, (linearity error or no linearity error, the analyzer uses as many measurement points as possible (min. 4) until either the curve decreases, the absorbance limits are exceeded or the substrate is depleted.

Incubation time

Endpoint Measurement Mode. If only R1 is used you can select between 11.5 min. and 4.5 min. If R2 is also used, the incubation time is fixed to 6.5 min. The incubation time refers to the time from addition of the last reagent or sample to the endpoint measurement.

Slope Blank

Kinetic and Two-point measuring Modes. If reagent 2 is used, select whether to use a Slope Blank. Press **ENTER**, select **Yes** or **No** from the drop down list and press **ENTER** to confirm. If **Yes** is selected, the analyzer subtracts the slope, calculated before R2 was added, from the slope that was calculated after R2 was added. The field **Slope Bl. Delay** is diplayed after selection of **Yes**.

Slope Bl. Delay

Appears if **Slope Blank** was selected with **Yes**. Press **ENTER** and select a time in seconds. Press **ENTER** to confirm. E.g. **50** is selected, the analyzer will use all the measurement points after 50 seconds (measured after the sample was added) for the calculation of the blank slope. The calculated blank slope is subtracted from the reaction slope (after addition of R2), when the results are calculated.

Point one, two

Twopoint Measuring Mode. Enter the first value to select a delay to the start of the first measurement for a twopoint test. This is necessary for incubation.. The second value has to be entered in the second drop down list to define last measuring point. The longest possible delay is 236 sec. in the **DUAL MODE** (422 sec. **MONO MODE**). Press **ENTER**, select a value and press **ENTER** again to confirm.

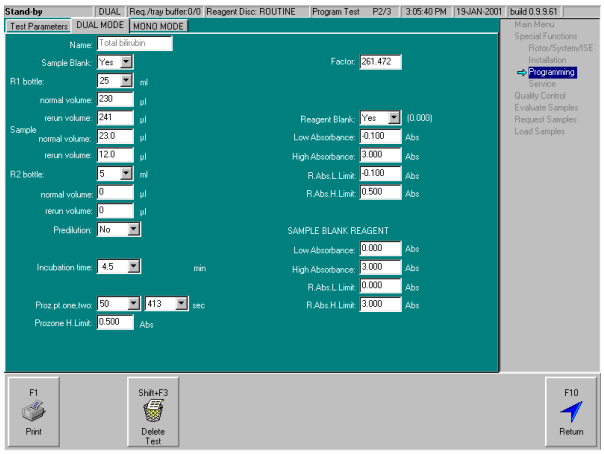
If > 0 was entered for the reagent 2 bottle in the field normal volume the values refer to the time after reagent 2 was added. If not, then the values refer to the time after the sample was added.

Proz. pt one,two

If an absorbance ratio or delta absorbance ratio were selected in the field **Prozone check** (Screen Page 1, Test Parameters), the field **Proz. point 1**, 2 is displayed here. Press **ENTER** to open a drop down list, select the time in seconds for the measurement of the first prozone point and confirm with **ENTER**. Repeat for the second point in the other field.

Proz. H. Limit

If an absorbance ratio or delta absorbance ratio were selected in the field **Prozone check** (Screen Page 1, Test Parameters), the field **Proz. H. Limit** is displayed here. Enter a high limit in form of an absorption or delta absorption per minute and confirm with **ENTER**. If this limit is exceeded, the analyzer displays a prozone error.



Linearity Limit

This limit is used to detect a linearity error for the first four measurements points and to evaluate the additional measurement points of a *kinetic* test that can be accepted for evaluation. The default value is 10%.

Factor

For methods that do *not* require calibration, the multiplication or Enzyme factor from the method sheet must be entered here. The factor is *negative* for a decreasing reaction. If a method uses a one-point-calibrator, the factor is automatically calculated and displayed in this field. If the factor is exactly 1.000, the analyzer concludes that the test was never calibrated. The results of this test are printed out with 3 decimal places and the unit abs, δ**abs** or δ**abs/m** (depending on the type of test, endpoint, twopoint, kinetic).

Reagent blank

Select whether or not a reagent blank measurement is to be used. Press **ENTER**, select **Yes** or **No** from the drop down list and press **ENTER** again to confirm. If you selected to carry out a blank measurement, a number after **Yes** appears that will contain the results of the reagent blank after measurement.

The reagent blank is the unspecific change in absorbance of the reagent solution if water is used as the sample. The result is subtracted from the absorbance change of the reaction with the sample.

Note

Do not confuse the reagent blank with the absolute absorbance measurement of the reagent, which automatically takes place for every test provided R1 volume > 220µl.

Low Absorbance

The **low absorbance limit** to be used. If a measured absorbance value is below this limit, the analyzer flags the result. An automatic rerun of the test starts if the **Automatic Rerun** option was selected in **SYSTEM PARAMETERS**.

High Absorbance

The high absorbance limit to be used. If a measured absorbance value is above this limit, the analyzer flags the result. An automatic rerun of the test starts if the Automatic Rerun option was selected in SYSTEM PARAMETERS.

R. Abs. L. Limit

The **reagent absorbance low limit** that is given in the method sheet. It is used to check the reagent absorbance before the sample is added. If the measured absorbance value of the first reagent is below this limit, the analyzer flags the result.

R. Abs. H. Limit

The **reagent absorbance high limit** that is given in the method sheet. It is used to check the reagent absorbance before the sample is added. If the measured absorbance value of the first reagent is above this limit, the analyzer flags the result.

Note

If the respective low and high limits are identical, no check will be performed by the system.

R. Abs. Deviation

This field is displayed if **0** was entered for the **R2 bottle** in the field **normal volume**. The value is only used for *decreasing* reactions. Here, the maximum deviation of the calculated (extrapolated) reagent absorbance value from the measured reagent absorbance value (point measured before the sample is added) is entered. The set value ensures detection of substrate depletion.

If the extrapolated reagent absorbance falls below the measured reagent absorbance minus the programmed reagent absorbance deviation, the result is marked with an error flag.

Substrate depletion

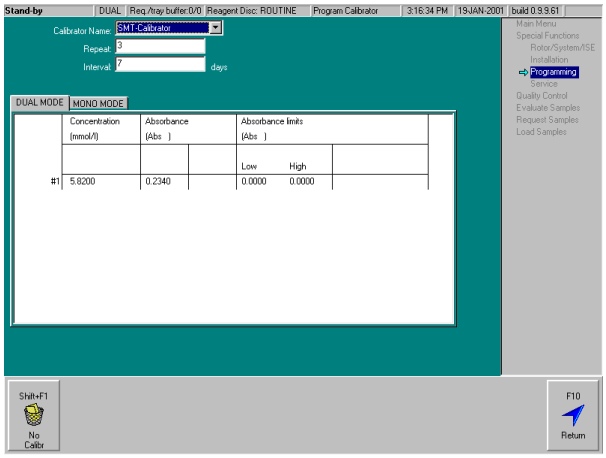
If the reaction increases, it is recommended to enter 3.000 abs.
If a value > 0 was entered for the **R2 bottle** in the field **normal volume**, this field will be displayed instead of **R. Abs. Deviation**. Enter the value given in the respective method sheet.

If the reaction *increases*, the analyzer *adds* this value to the point measured before reagent 2 was added; the resulting absorbance is the high absorption substrate depletion limit for this measurement.

If the reaction *decreases*, the analyzer *subtracts* this value from the last point measured before reagent 2 was added; the resulting absorbance is the low absorption substrate depletion limit for this measurement.
If this value is exceeded while the analyzer measures the first four kinetic points, the error message Substrate depletion will be displayed in the results report. The analyzer uses all absorbance values to calculate a result that has not exceeded the programmed limit value.

5.5 Calibrator parameter definition

After a calibrator has been selected in screen page 1 of the test parameter-programming screen all parameters that apply to this test must be programmed. The following screen appears:



5.5.1 Program Calibrator Parameters

Repeat

Defines a single, duplicate, or triplicate (1, 2 or 3) calibration. This value will also define the number of reagent blank measurements, if programmed. Enter a value and confirm with **ENTER**.

Interval

Enter the calibration interval in days (0 to 99) as shown in the method sheet. This number is the period in days when the method has to be re-calibrated. The analyzer includes the remaining days to the next calibration on the list with the daily cuvette blank measurement results. If 0 has been entered here, the analyzer only prints the test name without a mark on the list above and does *not* check the calibration interval.

Note

If the calibration interval has exceeded, the analyzer will keep on using the *expired* calibration factor or curve.

Concentration

Enter the concentrations of the standards (1 to 9 standards). These should have the same units as selected in screen page 1 (Test Parameters)

Absorbance

It is possible to fill in values copied from a previous calibration or another system.

It is not recommended to set these values manually. The values will vary in time and between systems. Results based on these values may be invalid.

The units here depend on the test; kinetic, twopoint or endpoint.

Absorbance Limits Low/High

Enter the **absorbance limit** for each individual standard. If a measurement exceeds the specified limits, the analyzer displays an error message (calibration limits violated). This is used to check if a standard has expired or if standards accidentally are exchanged.

If the same value is entered in both fields (e.g. 0.000), the calibration limits will not be checked.

SHIFT+F1 NO CALIBRATOR

Deletes the assignment of the current calibrator to the test. You may select a different calibrator in the TEST PARAMETERS screen

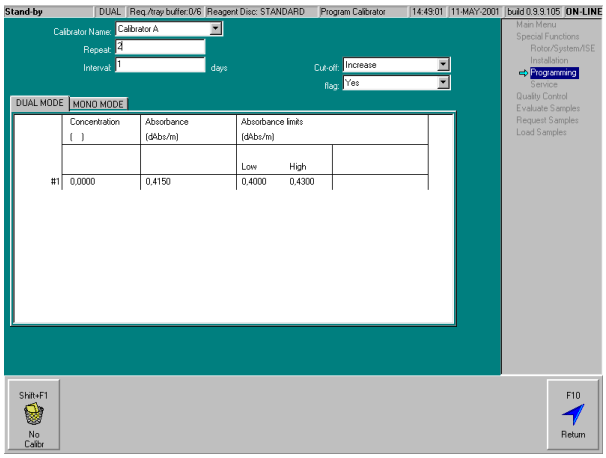
Slope/Intercept Only available if a TwoPoint calibration is required. These values represent the slope and the offset of the calibration line for a 2-point calibrator. The analyzer will automatically set the values in this column after calibration. The absorbance value can also be filled in by the user, but this is not recommended

5.5.2 Cut-off tests

If a calibrator has been programmed as a cut-off calibrator (one-point calibration) then any test that uses this calibrator is a cut-off test. In the **PROGRAM CALIBRATOR** screen the fields **Cut-off** and **Flag** will be displayed.
The result for a cut-off test is the measured absorbance value, delta absorbance or delta absorbance per minute, depending on the type of test and gives a **Positive** or **Negative** result.

To select Cut-Off

1. Press **ENTER** and select **Increase** (increasing curve) or **Decrease** (decreasing curve) from the drop down list. Press **ENTER** to confirm.
   1. If the measured (delta) absorbance is higher than the (delta) absorbance measurement of the standard then normally (increasing curve) the result is **POSITIVE**.
   2. If it is lower it is **NEGATIVE** and vice versa in case of a *decreasing* curve.
2. Select **flag** and press **ENTER**, select **Yes** or **No** from the drop down list. Press **ENTER** to confirm. If **Yes** is selected and the result is within value of the cut-off deviation (*grey area*) the analyzer prints an extra flag in the results report.



3. If **cut-off** and **flag** has been selected in the **PROGRAM CALIBRATOR** screen, then extra parameters will appear on pages 2 and 3 of the **TEST PROGRAMMING** screen. The following parameters appear on pages 2 and 3 of the **TEST PROGRAMMING** screen.

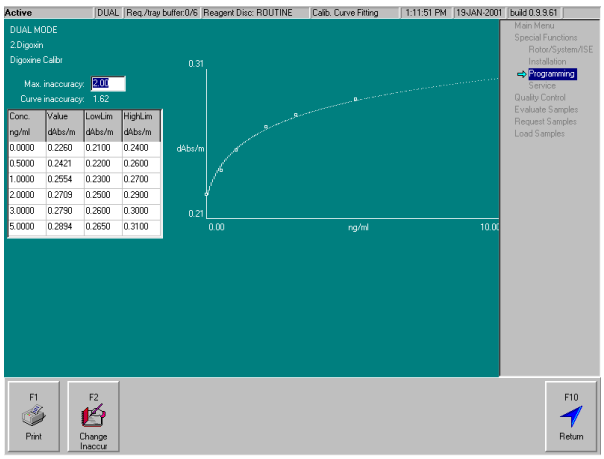
Cut-off value The result of the calibration. The analyzer displays the value of the cut-off calibration. The user can enter a value, but it is not recommended.

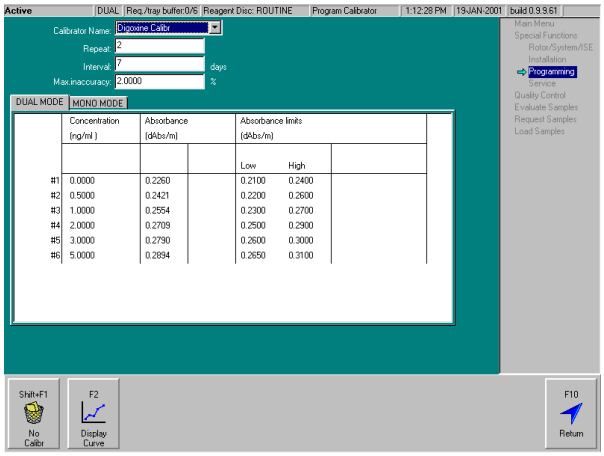
Cut-off dev Enter the Cut-off deviation that causes a flag.

Example: The result of a cut-off calibration was calculated to 0.120 delta abs/m. The cut-off was programmed as: **Yes**; **decrease**; **flag**: **Yes**; **cut-off deviation**: **+/- 0.010 delta abs/m**. The result of the sample is: 0.112 delta abs/m, POSITIVE since 0.112 is lower than 0.120 and flagged with an E as the deviation is -0.008 delta abs/m and is in the range of 0.120 +/- 0.010 delta abs/m.

5.5.3 Calibration Curves

If three or more standards (maximum 9) are used for calibration, the instrument produces a calibration curve at the end of the calibration procedure. From this curve the instrument uses the absorbance result to calculate a concentration. The values of the standards must be programmed in the **PROGRAM CALIBRATOR** screen.





F2 DISPLAY CURVE Display a graphical presentation of the calibration curve.

F1 PRINT Print out the calibration curve.

F2 CHANGE INACCUR Select the maximum value of imprecision. Enter the values as a percentage (%). If the value is changed, it is transferred to the test parameters. A new calculation is made and the analyzer will adjust the curve.

5.6 Needle/Cuvette Incompatibility

To avoid possible cross contamination, certain tests must never follow each other on the analyzer. There is a difference between **Needle incompatibility** and **Cuvette incompatibility**.
The user sets the analyzer for compatible and incompatible tests. Program the analyzer to the respective data sheets. The compatibility of tests must be checked and re-set when new test parameters are programmed.

Select from the **MAIN MENU, F5 SPECIAL FUNCTIONS**, **F3 PROGRAM**, **NEEDLE INCOMPATIBILITY** or **CUVET INCOMPATIBILITY**.

Incompatibility parameters

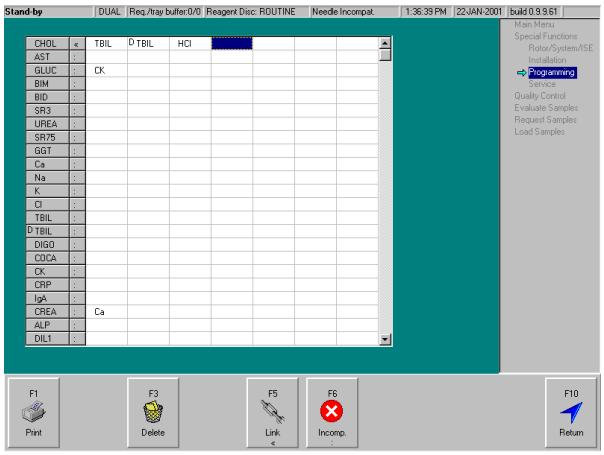
Needle incompatibility ALT : LDH — The reagent needle will not aspirate the LDH reagent immediately after the ALT reagent. The analyzer selects another test to be aspirated. If not HCl will be aspirated as an extra cleaning step.

Cuvette incompatibility ALT : LDH — A cuvette will not be used for the LDH test after ALT test. The analyzer selects another test for this cuvette. If not HCl will be dispensed as an extra cleaning step. This is after 48 cycles later.

Note: Be careful in setting incompatibilities as it decreases the throughput of the analyzer. Please consult your reagent supplier and/or distributor first before programming incompatibilities.

5.6.2 Display of Incompatibilities

The program procedure and display screen are identical for needle and cuvette incompatibility. All tests programmed in the analyzer are displayed on two pages. Incompatible tests are listed behind the respective abbreviate name of the programmed tests. A maximum of seven different tests can be set for each individual test.



Keys

ENTER	Display the test list and Select a test
CURSOR KEYS	Select a test or row
PAGE UP/PAGE DOWN	Scroll through the test list page by page
F1 PRINT	Print out the displayed screen
F3 DELETE	Delete the selected parameter
F5 LINK	Link the selected tests. The second test is processed directly after the first.
F6 INCOMP	Make the test incompatible. The second test is not processed directly after the first.
F10 RETURN	Return to the **NEEDLE** or **CUVET INCOMPATIBILITY** display

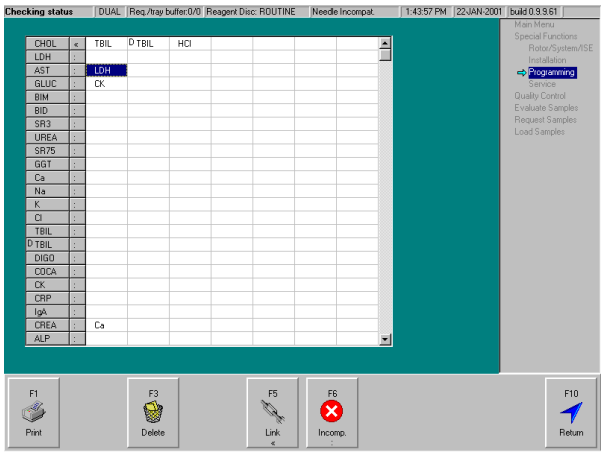
Note

A test with a superscripted ^{D} refers to the sample blank or "dummy" test, whereas a test without a ^{D} refers to the normal test.

5.6.3 Define Incompatibilities

The following refers to the **NEEDLE INCOMPATIBILITY** menu. To define **cuvette** incompatibilities, use the same procedure. The analyzer can hold up to seven incompatible and compatible tests for each test.

In this example, the test B must never be processed after test A.



1. Select from the **MAIN MENU**, **F5 SPECIAL FUNCT**, **F3 PROGRAM**.
2. Select **Needle Incompatibility**.
3. Press **ENTER** to activate the Needle incompatibility overview. Information on test definition is found in the method sheets for the reagents.
4. Place the cursor in the first column behind the test A.
5. Press **ENTER** to show a list of tests
6. Select the test B that must never go after test A.
7. Press **ENTER** to confirm. The analyzer will return to the incompatibility overview.

The default setting is that the test B is *incompatible* with test A. This setting is indicated by the colon (:) behind the test A.
If test A is very contaminating and no other reagent should be picked up by the reagent needle after the reagent A test then HCl must be linked to test A.

5.6.4 Define Linked tests

In this example, the test B must be processed after test A when possible.

1. Select from the **MAIN MENU**, **F5 SPECIAL FUNCT**, **F3 PROGRAM**.
2. Select **Needle Incompatibility**.
3. Press **ENTER** to activate the Needle incompatibility overview. Information on test definition is found in the method sheets for the reagents.Place the cursor in the first column behind the test A.
4. Press **ENTER** to show a list of tests.
5. Select the test that must go after test A.
6. Press **ENTER** to confirm. The analyzer will return to the incompatibility overview.
7. Select **F5 LINK** The colon changes to a link sign («).

The analyzer will now process test B directly after a test A, if possible.

Note

An o in front of a test name in column D in the incompatibility screen indicates that this test has a sample blank (dummy reagent). This dummy reagent can be selected by pressing F7 SELECT DUMMY **instead of** ENTER**.**

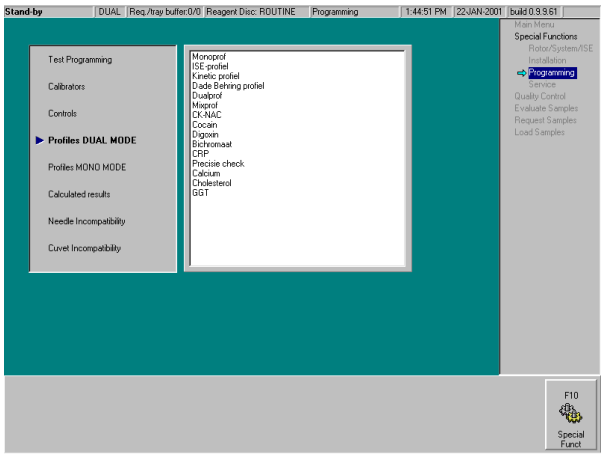
5.7 Profiles

Several tests can be combined to form profiles or panels. Once profiles are programmed, they are available to record test requests. Profiles can be programmed and changed when needed in the **PROFILES** menu. Profiles have to be set for **Dual** and **Mono Mode** separately. The procedure is identical for both modes.

5.7.1 Program PROFILES

1. Select from the **MAIN MENU**, **F5 SPECIAL FUNCTIONS**, **F3 PROGRAM**.
2. Select either Profiles **Dual Mode** or Profiles **Mono Mode.** The test profiles positions show.
3. Press **ENTER** to change to the input screen.
4. Select a profile name or an open position.
5. Change the name of the profile or program a new name.
6. Select the tests necessary for the profile. These tests can be changed later.

A maximum of 15 profiles can be programmed. Each profile name may consist of up to 20 characters.

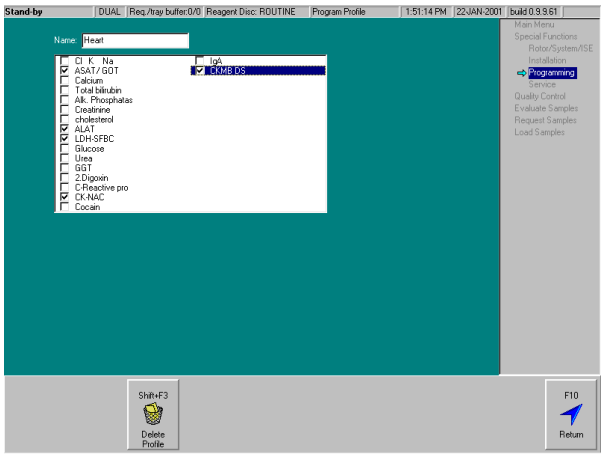


Keys

SHIFT+F1 DELETE PROFILE	Deletes the selected profile without confirmation
F10 SPECIAL FUNCT	Return to the **SPECIAL FUNCTIONS** menu
TAB	Change between the profiles list and the menu
CURSOR KEYS	Move within the list and select different profiles.
ENTER	From the menu, moves to the profiles list. From a specific position in the profiles list, change to the next screen with the list of tests

Note

While requesting patients you can also use the barcode reader with the tests request chart instead of a manual profile selection.



5.8 Reagent Position

Note

When you change to the right half of the screen by pressing TAB **or** ENTER**, the analyzer deletes all results in the** F7 EVALUATE SAMPLES **menu from the main memory without confirmation. They will only be saved to disk if option** Save Before Clear **was selected in** SYSTEM PARAMETERS**.**

After the test parameters are programmed the necessary reagents must be assigned to positions on the reagent rotor. This is done in the **INSTALLATION** menu.

Please note the difference between the **Dual Mode** and the **Mono Mode**. If you move between both modes, program each reagent position separately. It is recommended to use separate reagent rotors with separate bottle positioning for the two modes. If the mode is changed, it is then only necessary to replace the respective reagent rotor.

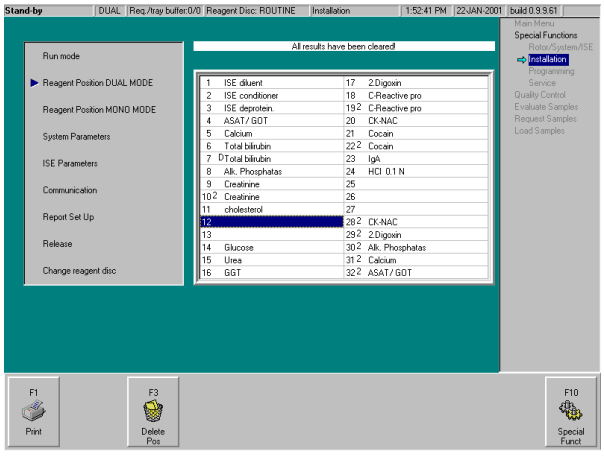
A table represents the 32 positions of the reagent rotor. When reagents are assigned, the test names are displayed on the corresponding positions. A superscript capital D in front of the reagent name indicates a sample blank reagent. A superscript 2 in front of the reagent name indicates a second or starter reagent.

If you wish to change an occupied reagent position, the analyzer will automatically delete all results that are currently stored on the main memory for that position. If you wish to occupy a free position using a new reagent, no results will be deleted. Use the Save before clear option in **SYSTEM PARAMETERS** if you want all results to be saved to disk.

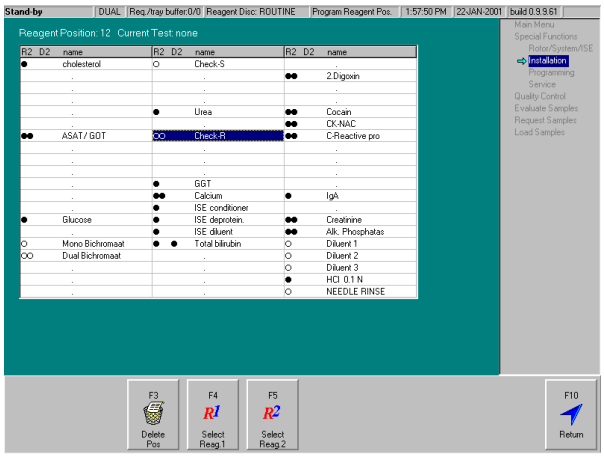
Only tests programmed in the **TEST PROGRAMMING** menu can be assigned a reagent position.

5.8.1 Program a REAGENT POSITION

1. Select from the **MAIN MENU, F5 SPECIAL FUNCTIONS, F2 INSTALLATION**.
2. Select **REAGENT POSITION DUAL MODE** or **REAGENT POSITION MONO MODE**
3. Press **ENTER**. The cursor moves to the selection field for the 32 reagent positions. All test results stored in the main memory are deleted. The message **ALL RESULTS HAVE BEEN CLEARED!** is displayed.
4. Select an empty rotor position, and press **ENTER**.
5. Select the required reagent for that position from the list, and press **F4**.-**Select Reagent 1.**
6. Place the bottle with the reagent 1 in the rotor at that position.
7. Select the next empty rotor position, and press **ENTER**.
8. Select the same reagent and press:
   - **F5** to select Reagent 2
   - **F7** to select Dummy 1
   - **F8** to select Dummy 2



9. Place the bottles for each reagent and dummy reagent in the correct position on the rotor.



Keys

TAB From the menu, moves to the position list. All results are deleted from the main memory.

CURSOR KEYS Move within the list/select a reagent position.

ENTER Change to the list of programmed tests.

F1 PRINT Print out a list of reagents and their respective positions on the reagent rotor.

F3 DELETE POSITION Deletes the selected reagent from the respective position. Remove the reagent from the rotor.

F10 SPECIAL FUNCTIONS Return to the previous menu.

F4 SELECT REAG 1 Assigns the selected test to the current position. This applies to both modes (MONO and DUAL) for reagent 1.

F5 SELECT REAG 2 Assign Reagent 2 of the selected test to the current position. This only applies to the **DUAL MODE**. A superscript 2 is displayed between position number and test name in the previous screen.

F7 SELECT DUMM.1 Assigns a dummy reagent (reagent blank) to the current position. This only applies to tests with reagent blanks defined. The superscript D in front of the test name is displayed in the previous screen to indicate the dummy reagent.

F8 SELECT DUMM.2 Assign dummy reagent 2 to the current position.

The columns contain a graphic representation that indicates whether the reagents exist and are installed

(*empty*) = reagent not defined in test parameters for this test

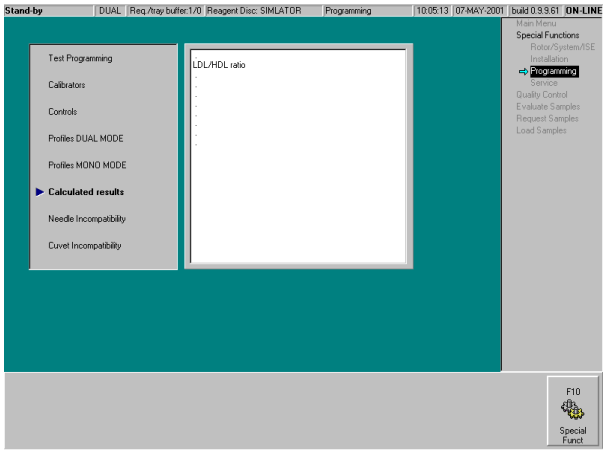
o = reagent not installed

● = reagent installed

In the **MONO MODE** no reagent 2 can be installed.

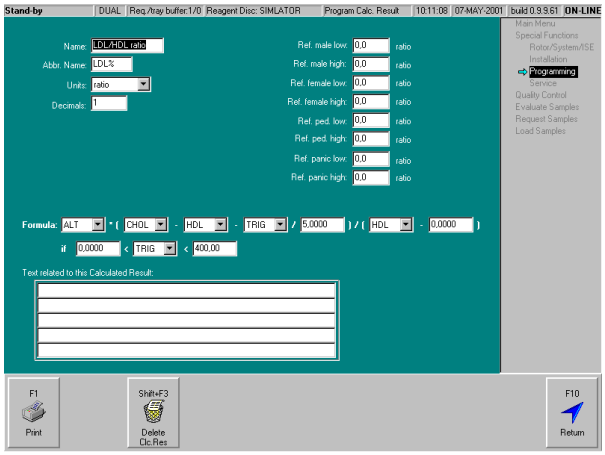
5.9 Calculated Results

Use a formula to derive a calculated result from other test results. The formula is set in the **CALCULATED RESULTS** menu.
Up to 10 formulas can be set. The results are not used for quality control.



5.9.1 Program Calculated Results

1. Select from the **MAIN MENU, F5 SPECIAL FUNCTIONS, F3 PROGRAM**.
2. Select **CALCULATED RESULTS** menu and press **ENTER**.
3. Select a previous entered name or an open position and press **ENTER**.
4. Type the following parameter fields.
5. Create a new formula by entering a value in each field or by selecting a test in each field. Combinations are possible.



Name — Name of the calculated result. If no name is entered here, the calculated result will not be stored.

Abbr. Name — The abbreviated name of the calculated result. If you create a new name, you have to specify an abbreviated name here. Otherwise, the calculated result will not be stored.

Units — The unit for the calculated result. By pressing **ENTER** a drop down menu shows the available units.

Decimals — The number of places after the decimal point.

Note

The screen contents changes depending on the type of units and number of decimals chosen. Enter the reference range values. Notice that the low limit values have to be lower than the high limit values.

Ref. male low	The low limit of the reference range for male samples. If a measured value is below this limit, the analyzer flags the result.
Ref. male high	The high limit of the reference range for male samples. If a measured value is above this limit, the analyzer flags the result.
Ref. female low	The low limit of the reference range for female samples. If a measured value is below this limit, the analyzer flags the result
Ref. female high	The high limit of the reference range for female samples. If a measured value is above this limit, the analyzer flags the result
Ref. ped. Low	The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.
Ref. ped. high	The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result
Ref. panic low	The low panic limit of the reference ranges for all samples. If a measured value is below this limit the analyzer flags the results on the print-out if the report set-up is enabled.
Ref. panic high	The high panic limit of the reference ranges for all samples. If a measured value is above this limit the analyzer flags the results on the print-out if the report set-up is enabled.
Formula	Here you can enter the formula for the calculated result at the cursor position. Buttons F5 and F7 become active when editing the formula. You can set a value in each of the formula fields or you can choose a pre set test.
Text related to this Calculated result	You can create a text to the calculated result. This will be printed on the results list only when the calculated results can be derived.

Keys

F1 PRINT	Prints the definition of the calculated test.
SHIFT+F3 DELETE CLC.RES	Deletes the definition of the calculated test.
F5 SELECT TEST	When the cursor is focused on a field in the formula that is selected as a test, pressing F5 opens a drop down menu allowing you to choose between the available tests.
F7 VALUE OR TEST	Toggles between value or test in a field in the formula.

Note

Printing of all calculated results is only performed if all data needed for the calculation is available, if the calculated test is programmed in the user defined report set-up and if the Use report lay-out **checkbox is checked in** SPECIAL FUNCTIONS**,** INSTALLATION**,** COMMUNICATION **menu. If a result cannot be calculated then the text related to this calculated result will not be printed.**

Example for printouts

PATIENT NAME: SMITH, MARY **ORDERING PHYSICIAN: C.M. JONES, M.D.**

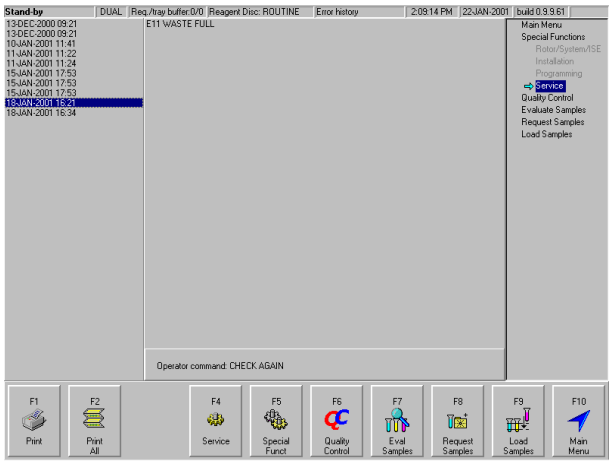
TEST	RESULTS		FLAGS	UNITS	REFERENCE RANGE
UREA	6		LOW	MG/DL	7 - 18
CHOLESTEROL	167	-		MG/DL	< 200
TRIGLYCERIDES	154	-		MG/DL	36 - 165
HDL	52	-		MG/DL	30 - 75
VLDL	3.1	-		MG/DL	10 - 38
LDL	84			MG/DL	66 - 178
%HDL	31		HIGH	%	20 - 30
CHOL/HDL RATIO	3.2			RATIO	2.7 - 6.7

	MEN	WOMEN
1/2 AVERAGE RISK	3.4	3.3
AVERAGE RISK	5.0	4.4
2X AVERAGE RISK	9.6	7.1
3X AVERAGE RISK	15.0	11.0

SODIUM	143		MEQ/L	136 - 145
POTASSIUM	2.0	PANIC	MEQ/L	3.5 - 5.1

NAME OF YOUR LABORATORY

5.10 Error Flags and Messages



The analyzer constantly checks its settings, even during sample processing, test programming or in the stand-by mode. Each deviation from the set reference values is immediately displayed on the screen in form of messages.

An error message informs the user about operating errors and system errors and faults with the corresponding action to take. For example: insufficient liquids in the system and errors in the system setting. The most important error messages are described in chapter 6.

In this chapter, the error flags, causes and actions to take are described. Some of the functions related to error flags and the actions required are described too. Some messages are accompanied by acoustic signals. Pressing a key (e.g. space) stops the signal.

There are several ways for the user to react, if a message is displayed. For each alternative a key or key combination has to be pressed. The analyzer displays the respective keys and their function on the monitor.

Keys

F1 Check Again — Repeats the procedure that led to the error message if the importance of the message is unclear. Take action if the message is displayed again.

F2 Confirm refill — This key is only available if a message is displayed for insufficient amounts of reagent. In this case, replace or refill the reagent bottle on the reagent rotor and then press **F2**. The error message will be cleared from the screen.

F4 Acknow message — (Acknow. Message) This key is only available, if the message displayed on screen requires no immediate action.

F5 Reset — Partly resets the analyzer. This key is only available if the message is related to a specific component of the analyzer. The reset is carried out for the respective displayed component. If the measure is successful, the analyzer continues. Press **SHIFT+F6** if pressing **F5** was not successful (system does not work).

SHIFT+F6 System reset — Resets the analyzer. Only use **SHIFT+F6** if the message cannot be cleared from the screen using the other keys. Inform the service technician if the message is displayed again after a reset!

SHIFT+F7 Remain inactive — The analyzer status remains inactive. The analyzer cannot continue with the operation. It can only be brought back to the stand-by mode by triggering reset. Inform the service technician.

ALT+F10 Halted — The analyzer stops all current operations. The line analyzer status (upper left side of screen) displays the word HALTED.

Note

Check the error history, before you call the technical service. See chapter 6.

5.1.1 Error flags

For certain errors the test results are marked with a flag. The cause and necessary action are described below. Further information about troubleshooting is given in chapter 6.3.

Error flag	Cause	Action
G	General hardware error. A hardware error was ignored by the operator.	Use the error list in the **ERROR HISTORY** menu to find the cause of this error. Select **F1 RESET SYSTEM** in the **RESET SYSTEM** menu to clear this error. Otherwise inform service.
R	Insufficient reagent.	Fill the empty reagent bottle with reagent. Press **F2 Confirm Refil** to confirm.
#	Insufficient sample.	Make sure the sample is, of sufficient volume, not coagulated and no air bubbles block the sample aspiration.
L	Cuvette blank error.	Check the results of the last cuvette blank measurement in the **BLANK ROTOR** menu. Repeat the blank measurement if required.
	Lamp error.	Adjust or replace photometer lamp.
U	Cuvette blank error.	Check the results of the last cuvette blank measurement in the **BLANK ROTOR** menu. Repeat the blank measurement, if required.
	Underrange.	Adjust or replace photometer lamp.
O	Cuvet blank error.	Check the results of the last cuvette blank measurement in the **BLANK ROTOR** menu. Repeat the blank measurement, if required.
	Overrange	Adjust or replace photometer lamp.
U	Cuvet blank error.	Check the results of the last cuvette blank measurement in the **BLANK ROTOR** menu. Repeat the blank measurement, if required.
	Underrange reference detector	Inform service.
	Error in electronics.	Inform service.
O	Cuvet blank error.	Check the results of the last cuvette blank measurement in the **BLANK ROTOR** menu. Repeat the blank measurement, if required.
	Overrange reference detector.	Inform service.
	Error in electronics.	Inform service.
T	Cuvette temperature error.	Inform service.
R	Rerun.	A test was re-run with pre-diluted volume.
*****	Non-linearity error.	A non-linear reaction of kinetic tests on the first four measurement points.

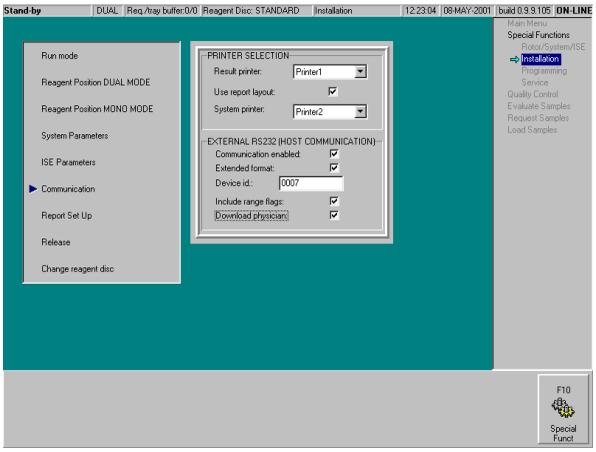
Error flag	Cause	Action
X	Concentration limit error.	The limit set in the **TEST PROGRAMMING** menu was exceeded.
D	Reagent absorbance deviation error.	Select **F6 RERUN MEASUREMENT** in the **EVALUATE SAMPLES** menu.
	The limit set in the **TEST PROGRAMMING** menu was exceeded.	Select **F6 RERUN MEASUREMENT** in the **EVALUATE SAMPLES** menu.
A	Reagent absorbance limit violation.	Make sure the limits in the **TEST PROGRAMMING** menu are correct. Prepare fresh reagent solution if necessary.
A	Calibrator limit violation.	Compare the values set in the **TEST PROGRAMMING** menu with the data given in the insert sheet of the test. Prepare fresh calibrator or reagent solution if necessary.
C	Control limit violation.	Compare the values set in the **TEST PROGRAMMING** menu with the data given in the insert sheet of the test. Prepare fresh control or reagent solution if necessary.
N	Reference limit violation. The reference limit was exceeded.	
W	Westgard rules limit violation.	Compare the results of the quality control of all controls set for this test. Prepare fresh control or reagent solution or calibrate the test, if necessary.
P	Prozone error.	Repeat the measurement with pre-diluted sample.
E	Result near cut-off.	The result lies within the set cut-off deviation programmed in the **TEST PROGRAMMING** menu.
M	Absorbance limit violation.	The limits set in the **TEST PROGRAMMING** menu are exceeded.

Special functions

6.1 Select printers and set host connection

If the analyzer is to be connected to a Lab-EDP System, or if a printer is to be installed, connections and specifications of these devices must be defined.

1. Select: **MAIN MENU, F5 SPECIAL FUNCTIONS, F2 INSTALLATION, COMMUNICATION.**



Parameters

Result printer

Select a printer for all patient results. Select Off to disable printing of patient results temporarily. Any printer supported by Windows can be selected.

The result printer will print patient results in a standard format if no report set-up is defined or the report set-up is disabled.

Use report layout

☒ The result printer uses the user defined report set-up.

☐ The result printer uses the default report set-up.

System printer

Select a printer for all non-patient result data like graphs, blank data, calibration curves, etc. Any printer supported by Windows can be selected.

If both printers are set to Off no data will be printed.

Communication enabled

☒ Enable communication with a host computer. (ON-LINE)

☐ Disable communication with a host computer. (Default)

Extended Format

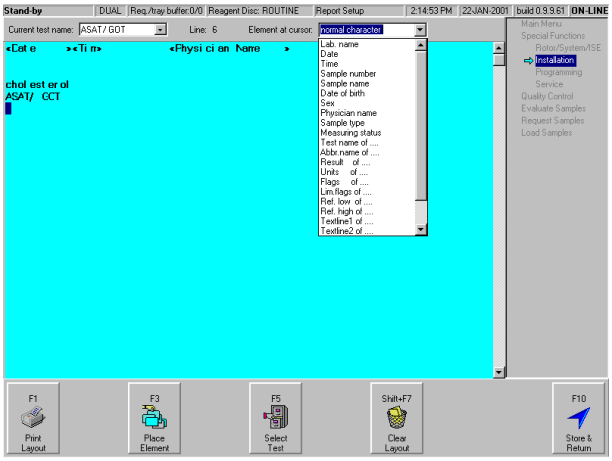
☒ Use an extended format (absorbance values are transmitted to the host along with the results).

Device id.

Enter a four-digit code for identification purposes. All information sent to the host computer will be identified by this code.

6.2 Set up a report

If a special result printer is to be used for result printouts, the printout format has to be defined in the Report Set Up menu. The layout of the reports can be individually defined. You can define which information is to be printed out, and also which position it should have on the paper.



1. Select: **MAIN MENU, F5 SPECIAL FUNCTIONS, F2 INSTALLATION, REPORT SET UP.**
2. Press **TAB** or **ENTER**.

In the report set-up, it is possible to write text like you would do with a normal word processor, but you can also add parameter fields with a variable content.

The words between the brackets « and » in the figure below are the parameter fields, which will be replaced by the actual contents of the parameters at the time of printing.

3. Select **F3 PLACE ELEMENT** to define the test attributes, e.g. abbreviations and units of measurement and position the field. Otherwise, the results of a test will not be included in the result report.
4. Select **F5 SELECT TEST** to select the tests.

Note

If a test is not positioned (i.e. not displayed in the layout), the results are not printed out in the result report, even if the test was requested and measured. Therefore, make sure that the required test is positioned when setting up a report.

5. Select **F10 STORE & RETURN** to save the new layout and return to the previous menu.

The analyzer will now layout the printouts.

Keys

F1 PRINT LAYOUT	Print out the report layout. This is only possible if a result printer is activated in the **COMMUNICATION** menu.
F3 PLACE ELEMENT	After pressing **F3**, select an element from the drop down list and press **ENTER** to place it at the cursor's current position. Position the cursor on the desired place first to position an element
F5 SELECT TEST	Select a test from the drop down list and confirm with **ENTER**. Test-specific elements, placed with **F3**, refer to this test.
SHIFT+F7 CLEAR LAYOUT	Clear the layout completely without confirmation!
F10 STORE AND RETURN	Save the current layout and return to the previous screen.
CURSOR KEYS	Position the cursor on the screen.

6.3 Troubleshooting

The analyzer reflects the most up-to-date technological standards and was designed to be as user-friendly as possible. It constantly monitors all functions and informs the user about operating errors and system malfunctions. However, in technical systems operating errors and certain system malfunctions can never be fully excluded, especially since mechanical components are always subject to wear. The most frequent malfunctions caused by wear are described in the following chapter. A great number of these can be solved without assistance from the technical service personnel.

Note

Check the error history, before you call the technical service. See 6.3.4.

6.3.1 Defective mixer belt

If you notice invalid measuring results marked with a flag, the cause of which is unclear, the reason could be a defective mixer belt. It can be acoustically detected: the typical mixing sound is missing. Moreover, neither the sample needle nor the reagent needle rotates during mixing (the reagent needle only rotates if reagent 2 was added).

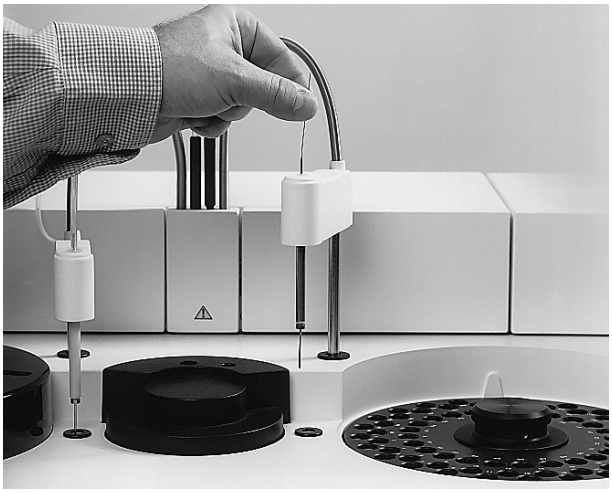
The mixer belts must be checked daily before running the routine. Replace the mixer belt if it looks worn or if it is broken:

1. REMOVE the old belt from the support. If the belt is destroyed, remove the parts from the area around the cuvette rotor.
2. Pull the new mixer belt (part of the range of supply) over the support until it is correctly positioned.
3. Put the cuvette rotor lid back in its place.

6.3.2 Sample needle clogged

Take following actions if the sample needle is clogged:

1. Press **ALT+F10**.
2. Carefully pull the tube, consisting of an outer and an inner part, off the sample arm.



Attention: The sample needle has a double wall. Do not push the double-tube inwards when it is pulled off and put back into its place after cleaning.

3. Take the stylet that is part of the range of supply and carefully push it into the inner needle from above until it comes out at the end of the needle.
4. Carefully move the stylet up and down several times to remove all substances that block the needle. Do not dispose the stylet afterwards.

When the tube is put back into its place, ensure that the outer protective tube is **not** pushed into the opening of the needle cover. Only the inner tube has to be pushed into the needle cover. After the tube has been correctly fixed and the analyzer has been reset, operation can be continued.

6.3.3 Removal of rotor tray

Should you detect any liquids or objects on the bottom of the rotor trays (sample and reagent tray), the respective tray must be removed and cleaned.

1. Press **ALT+F10**.
2. Turn the screw cap counter clockwise until it can be removed.
3. Remove the tray.
4. Now clean the bottom of the rotor tray or remove the object from the rotor tray.

After putting back the rotor do not forget to place the screw cap (turn clockwise).

6.3.4 Error history

Note

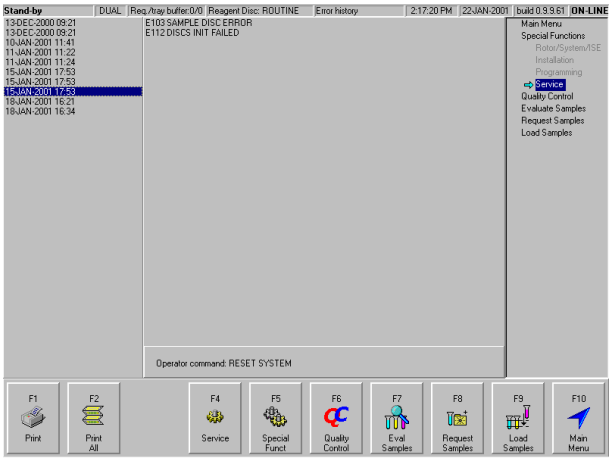
Malfunctions are often caused by the fact that the mentioned cleaning procedures were not performed often enough (i.e. not in accordance with the maintenance plan). You can check the needle rinse history by activating the corresponding item in the SERVICE menu.

Use this function in case of problems to inform the technical service personnel on what type of error (and error number) has occurred.

The easiest and fastest way to inform the technical service about the detected malfunctions is to send the printout to the respective service technician per fax.

1. Select: **MAIN MENU, F4 SERVICE, ERROR HISTORY**
2. Press **TAB** or **ENTER**.

Each error message displayed by the analyzer is documented here.



On the left side of the display date and time of an error is displayed. The right-hand side shows the corresponding error number and an error description. The analyzer also documents which measures the user took, i.e. which keys were used. Use the cursor keys to scroll through the list of messages.

3. Select **F2 PRINT ALL** to print out the entire error history.

Keys

F1 PRINT	Print out the selected error message including date and time of occurrence.
F2 PRINT ALL	Print out the complete list of error messages including last needle rinsing and last system cleaning data. Make sure, there is enough paper in the printer!
F4 SPECIAL FUNCTIONS	Switch to the **SERVICE** menu.
F5 SPECIAL FUNCTIONS	Switch to the **SPECIAL FUNCTIONS** menu.

FUNCTIONS

F6 QUALITY CONTROL	Switch to the **QUALITY CONTROL** menu.
F7 EVAL SAMPLES	Switch to the **EVALUATE SAMPLES** menu.
F8 REQUEST SAMPLES	Switch to the **REQUEST SAMPLES** menu.
F9 LOAD SAMPLES	Switch to the **LOAD SAMPLES** menu.
F10 MAIN MENU	Return to the **MAIN** menu.

6.3.5 Error code lis

The error messages displayed by the analyzer can be divided into two groups: **flag-error messages** and **hardware-error messages**.

Error Messages (Flags). Refer to chapter 5.3.

Flag-error messages are printed behind a test result. Error messages that are marked with an asterisk (*) in the list below are also displayed on screen and can be recognized by an acoustic signal, which can be stopped by pressing the space bar.

Error messages that are not marked will be printed out.

* **INSUFFICIENT REAGENT**
* **NO REAGENT TAKEN**
* **REAGENT PIPETTING STOPPED**
* **LAMP UNDERRANGE**
* **LAMP OVERRANGE**
* **LAMP UNDERRANGE REF CHANNEL**
* **LAMP OVERRANGE REF CHANNEL**
INSUFFICIENT SAMPLE
LINEARITY ERROR
ABSORBANCE LIMIT ERROR
REAGENT ABSORBANCE DEVIATION ERROR
REAGENT BLANK LIMIT ERROR
CALIBRATION LIMIT ERROR
CONTROL LIMIT ERROR
REFERENCE LIMIT ERROR
REAGENT ABSORBANCE ERROR

Error message	Cause	Action
INSUFFICIENT REAGENT	Safety switch of the reagent needle is activated (bottle empty). Liquid detection of the reagent needle is not detecting any liquid (bottle missing or empty). Liquid detection is not working.	
NO REAGENT TAKEN	Filling level of the reagent bottle is too high (e.g. filling level is near screw-cap). Foam is being produced.	
REAGENT PIPETTING STOPPED	The reagent needle could not be cleaned and therefore stopped pipetting.	Make sure HCI is installed on the reagent rotor and its bottle is not empty.
LAMP UNDERRANGE	A counter overrange (> 29 000) is detected during a measurement.	Refer to hardware error LAMP FAILURE.
LAMP OVERRANGE	A counter underrange (< 10) is detected during a measurement.	Refer to hardware error LAMP FAILURE.
LAMP UNDERRANGE REF CHANNEL	A counter overrange (> 29 000) for the reference detector is detected during a measurement.	Refer to hardware error LAMP FAILURE.
LAMP OVERRANGE REF CHANNEL	A counter underrange (< 10) for the reference detector is detected during a measurement.	Refer to hardware error LAMP FAILURE.
INSUFFICIENT SAMPLE	The safety switch of the sample needle is activated (sample cup empty). Liquid detection of the sample needle is not detecting any liquid after aspirating the sample (detection of air bubbles).	

Hardware-error messages

Hardware-error messages are displayed on screen and can be recognized by an acoustic signal, which can be stopped by pressing the space bar. The most important hardware-error messages will be explained below. Errors that can be eliminated by the user himself, will be described in detail.

In general, many errors cause other errors at the same time. For example, a wash arm error (E122) also causes a system emergency halt (E02). When the most obvious error is solved, usually also the other error disappears.

Error message	Cause	Action
E02 SYSTEM EMERGENCY HALT	For example the ISE arm was accidentally touched during measurement. The analyzer immediately interrupts all operations.	Eliminate the error if possible and select **SHIFT+F6 SYSTEM RESET**. The analyzer then asks you on the screen, whether the interrupted measurements, the results of which were cancelled, should be repeated.
E05 NO CLEAN CUVETTE	If no clean cuvette is available on the cuvette rotor, (e.g. caused by a vacuum error), the wash arm with the dry block does not move down to the bottom of the cuvette to prevent contamination of the dry block. Thus no clean cuvette is available in the analyzer.	Eliminate the error if possible (for example, clean and dry the rotor manually, install a new one or refill it) and select **SHIFT+F6 SYSTEM RESET**. If the error occurs again, inform the service technician.
E07 SYSTEM RESET INCOMPLETE	Due to further errors the system reset was incomplete.	Eliminate the error if possible and select **SHIFT+F6 SYSTEM RESET** to repeat a reset. If the error occurs again, inform the service technician.
E10 NO VACUUM The vacuum is not sufficient for a period longer than 2.5 seconds.	Vacuum pump defective. Vacuum tubing defect or clamped. Vacuum sensor defective or not well adjusted.	Select **F1 CHECK AGAIN** and inform the service personnel. Check that the tubing that connects the analyser with the pump unit or the analyser with the bottles is not kinked or clogged. **Service personnel only:** Check if the vacuum pump is working properly and replace the membrane or the complete vacuum pump, if necessary. Check the vacuum tubing for leakage. Check the vacuum sensor and re-adjust it, if necessary.

Error message	Cause	Action
E11 WASTE FULL	The WASTE FULL signal is "high" for 1 second (or longer).	Empty the waste container. Check if the waste container floating switch is working properly and replace/repair it, if necessary. Check the wiring. **Service personnel only:** Check if the waste full signal detection signal is present on the system board. When the signal is present, malfunctioning of the system board may cause the problem.
E12 WATER RUNNING OUT	The upper level detector detects "No water" in the water container, although the pump is switched on for a period longer than 25 seconds.	Check if there is enough system liquid in the water container and refill, if necessary. Check if the water tubing is leaking or blocked and repair or replace defective tubes, if necessary. Check if the filter in the system liquid container is blocked and replace it, if necessary. If the waste container has been empty, hold the water container and the pump unit at a higher level, to assure that the water can reach the analyser more easily. **Service personnel only:** Check if the liquid level detection circuit is working correctly and repair it, if necessary.

Error message	Cause	Action
E13 LAMP FAILURE	A counter over range signal is detected during a measurement. The signal counter over range signal is generated when the photocell signal is too low. When the blank data values are incorrect too, the gain setting of an input amplifier is wrong or an input amplifier is defective (on the photometer board).	Select **F1 CHECK AGAIN**. If the error occurs again, check if the lamp is working and replace it, if necessary. Inform the service technician. **Service personnel only:** Check if the lamp voltage is present and well adjusted. Adjust or repair the voltage supply, if necessary. Check if the selected filter is in the filament of the lamp. If not, check if the transport of the filter wheel is working correctly. Find the failure by following the adjustment procedure (submenu **ELECTRONICS**) in the **SERVICE** menu if a defective or incorrect set input amplifier causes the problem. Check that the lamp intensity is not too high (infinity signs on the intensity bars in the **LAMP ADJUSTMENT** menu).
E14 CUVETTES TEMP ERROR		Select **F1 CHECK AGAIN**. Inform the service technician if the error occurs again.
E15 REAGENT NEEDLE TEMP ERROR		Select **F1 CHECK AGAIN**. Inform the service technician if the error occurs again.
E16 CONCENTRATED WASTE FULL (only if the optional container is installed)	The CONC. WASTE FULL signal is "high" for 1 second (or longer).	Empty the optional concentrated waste container. Check if the concentrated waste container floating switch is working properly. Check the wiring.

Error message	Cause	Action
E17 INSUFFICIENT WATER	The lower level detector detects "No water" in the water container.	Check if there is enough system liquid in the container and refill if necessary. Check if the liquid tubing is leaking or if it is blocked and repair if necessary. Check if the filter in the container is blocked and replace if necessary. **Service personnel only:** Check if the system liquid level detection circuit is working correctly and repair if necessary.
E20 SAMPLE SYR. POS. ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E21 SAMPLE SYR. POS. ERROR		
E22 SAMPLE VALVE ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E23 REAG. SYR. POS. ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E24 REAG. SYR. POS. ERROR		
E25 REAG. VALVE ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E30 PIPETTOR 14V FAILED		Inform the service technician.
E31 PIPETTOR 30V FAILED		
E35 SAMPLE SYR. RESET FAILED		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E36 REAGENT SYR. RESET FAILED		
E37 PIPETTOR COMMUNICATION ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.

Error message	Cause	Action
E40 MEAS. DISC 14V FAILED		Inform the service technician.
E41 MEAS. DISC 30V FAILED		
E42 MEASUREMENT DISC ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E43 FILTER ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E55 MEAS. DISC RESET FAILED		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E56 FILTER RESET FAILED		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. Inform the service technician if the error occurs again.
E57 MEAS. DISC COMMUNICATION ERROR		Inform the service technician.
E60 SAMPLE ARM 14V FAILED		Inform the service technician.
E61 SAMPLE ARM 30V FAILED		
E62 SAMPLE ARM HORIZONTAL ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E63 SAMPLE ARM VERTICAL ERROR		
E75 SAMPLE ARM RESET FAILED		
E76 SAMPLE ARM RESET FAILED		
E77 SAMPLE ARM COMMUNICATION ERROR		
E80 REAGENT ARM 14V FAILED		Inform the service technician.
E81 REAGENT ARM 30V FAILED		
E82 REAGENT ARM HORIZONTAL ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E83 REAGENT ARM VERTICAL ERROR		
E95 REAGENT ARM RESET FAILED		
E96 REAGENT ARM RESET FAILED		
E97 REAGENT ARM COMMUNICATION ERROR		
E100 DISCS 14V FAILED		Inform the service technician.
E101 DISCS 30V FAILED		

Error message	Cause	Action
E102 REAGENT DISC ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E103 SAMPLE DISC ERROR		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**.
E115 REAGENT DISC RESET FAILED		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**.
E116 SAMPLE DISC RESET FAILED		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**.
E117 REAG. /SAMP. DISCS COMMUN. ERROR		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**.
E120 WASHARM/BELLOWS PUMP 14V FAILED		Inform the service technician.
E121 WASHARM/BELLOWS PUMP 30V FAILED		
E122 WASHARM ERROR		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**. Make sure the cuvette rotor is placed correctly.
E123 BELLOWS PUMP ERROR		Press either **F5** (Specific Reset) or select **SHIFT+F6 SYSTEM RESET**. Note that this error often occurs with other errors. First try to solve the other errors. This error might also disappear then.
E124 WATER OVERFLOW MEASUREMENT DISC	The wash arm detects that liquid reaches its overflow sensors.	In the halted or inactive state remove the cuvette cover, and then continue running. Determine which of the causes 1, 2 or 3 is the case and take the respective action.
	1. The wash arm dispenses too much water. Probably all cuvettes under the wash arm show a water overflow.	1. Check that the tubing between pump unit and main unit and the tubing between pump unit and the bottles is not bent or clogged.

Error message	Cause	Action
	2. Some or all needles of the wash arms do not aspirate correctly. Probably only a few cuvettes show water overflow.	2. In the **CHANGE ROTOR** menu lift the wash arm and clean with the cleaning rod the aspiration needles (long needles). Also see 1. **Service personnel only:** Check the vacuum and valve 2 and 4.
	3. The message looks erroneous. There is no clear overflow. There is a cause for conductance between the overflow sensors on the wash arm and the plate of the wash arm.	3. Lift the wash arm and clean the underside of the wash arm, especially around the overflow sensors. **Service personnel only:** Check the overflow signal; replace wash arm if necessary.
E125 NO CUVETTES	There is no cuvette rotor installed At resetting the wash arm can reach a too low position according to the opto read-out.	Check if a cuvette rotor is present and place one, if necessary. Then press **F5 SPECIFIC RESET**. **Service personnel only:** Check if the wash arm adjustment is correct. Check if the opto-couplers are malfunctioning and repair them, if necessary. Check if the wash arm is well tightened.
E135 WASHARM RESET FAILED		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**. See also E122 washarm error.
E136 BELLOWS PUMP RESET FAILED		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.
E137 WASHARM/BELLOWS PUMP COMM. ERROR		Press either **F5 SPECIFIC RESET** or select **SHIFT+F6 SYSTEM RESET**.

6.4 Maintenance procedures

The analyzer has very low maintenance requirements. However, it is important that the maintenance procedures are strictly followed. All maintenance steps are described in the following table.

Attention

Liquid waste is potentially infectious and can be hazardous to health. It must be disposed of according to national and international instructions for the safe disposal of biohazardous waste. All laboratory-specific safety precautions have to be strictly followed for the cleaning of the analyzer, since contamination with infectious materials can never be fully excluded.

6.4.1 User Maintenance

Perform the **daily maintenance** before daily routine.

There is no end-of-day procedure that must be followed. Just before going into standby mode the instrument will automatically clean the reagent needle with the HCI-solution that is on the reagent wheel and the sample needle with the Sputofluol solution that is on the W position on the sample wheel.

Perform the **weekly maintenance** at the end of the week.

DAILY	1. Fill water container with system liquid and distilled water (25 ml system liquid on a full 10 liter container). 2. Empty the waste container (follow the safety instructions for working with potentially infectious material!). 3. Check cuvette rotor blank results. 4. Replace cuvette rotor if necessary. 5. Check printer paper. 6. Fill HCl-bottle in the reagent rotor with 0.1 mol/l HCl. 7. Fill tube in W-position of sample rotor with Sputofluol 10%. 8. Fill tube in B-position of sample rotor with distilled water. 9. Remove cuvette cover and check wash arm, mixers and cuvette rotor visually. 10. If the ISE option is used, fill tube in ISE position with human sample (activator).
WEEKLY	1. Perform needle rinse procedure: cleaning of sample and reagent needle with Sputofluol 10%. 2. Check syringes and Teflon tips on air bubbles and leakage; clean syringes or replace tips if necessary.
MONTHLY	1. Clean water and waste container(s) with 0.1 mol/l NaOH. Afterwards rinse several times with water.
QUARTERLY	1. Replace mixer belts. If not done by the service technician during preventive maintenance: 2. Replace water filter. 3. Replace drying block on wash arm.
SEMI-ANNUAL	1. Run the clean system procedure with 100% Sputofluol During the clean system procedure the instrument is completely rinsed with a concentrated cleaning solution which takes about 3 hours, during which the operator has to change liquids and tubings a few times. Because tubings or valves might clog during the clean system procedure, it should *only be performed after consulting your supplier*.
AS NEEDED	1. Replace cuvette rotor (after 10 000 tests or after SD-error after cuvette blank). 2. Replace lamp.

6.4.2 Replace measurement disk

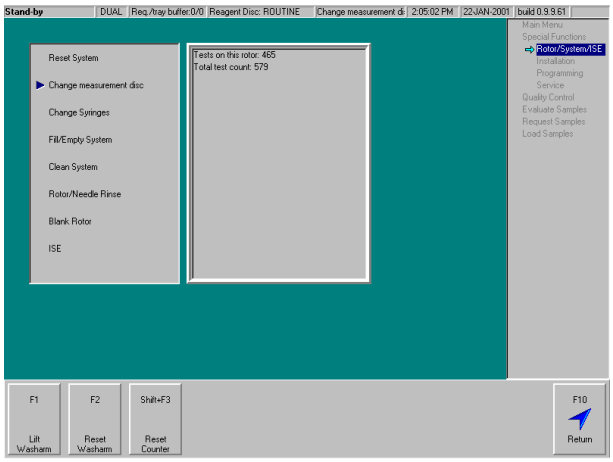
The measurement disk (cuvette rotor) must be replaced after 10 000 tests or when an SD-ERR appears on the print-out after the cuvette blank. If the counter of the system has recorded more than 10 000 tests, an error message is displayed on the screen.

You can reset the counter to zero and cancel the error message by pressing **SHIFT+F3**. **Ignoring this message may result in incorrect results**.

1. Remove all samples.

   Check that the analyzer is in standby.
2. Select: **Change Rotor** in the **ROTOR/SYSTEM** menu.
3. Remove the rotor cover from the cuvette rotor.
4. Select: **F1 LIFT WASHARM.**

   The system will lift the wash arm.
5. Lift the mixer unit manually.
6. Remove the rotor.



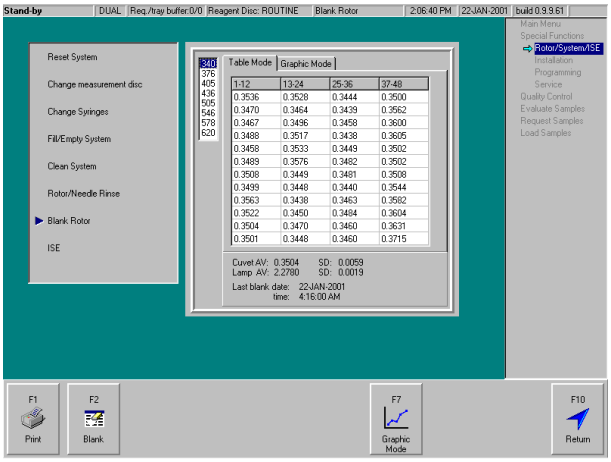
Attention

Observe all common safety precautions (e.g. wear gloves), since this part of the system is potentially infectious. Also make sure that no liquids leak into the analyzer system.

7. Unpack a new rotor.

   Do not to touch the sides of the rotor, but hold it by its center hold.
8. Place the new rotor while assuring that the four notches of the rotor fit in the slits of the rotor holder.
9. Press the mixer unit down.
10. Select **F2 RESET WASHARM** to lower the wash arm.
11. Place the cover.
12. Answer the question displayed on the screen.

    After selecting **Yes** the system will reset the counter to zero.
13. Perform a cuvette rotor blank measurement.

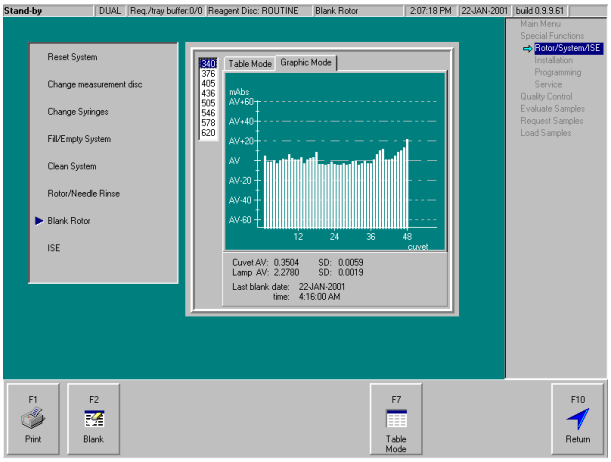


6.4.3 Manual Cuvette Rotor Blank Measurement

Once a day a cuvette rotor blank measurement must be performed. The analyzer can carry this out automatically, if the **Automatic Blank Time** was set in the **SYSTEM PARAMETERS** menu. For an automatic blank measurement the analyzer has to be in the stand-by mode. Cuvette rotor blank measurements can also be performed manually. It has to be carried out manually after the first installation of the system and after replacement of the cuvette rotor (see previous section). A manual cuvette rotor blank measurement is started in the **BLANK ROTOR** menu.

After the menu is called up the system displays all absorbance values for the 48 cuvettes. The values for the cuvette AV and the lamp AV are displayed together with the respective standard deviations SD.

The graphic mode shows a graphic representation of the blank measurement results.



Keys

TAB or **ENTER** ARROW KEYS	If in the menu, move to the right side of the display. Selected a wavelength.
F1 Print	Print out the current display.
F2 Blank	Start the cuvette blank measurement. This is only possible when the system is in “stand-by” mode, thus not processing samples. This takes about 13 minutes.
Enter OR F7 **GRAPHIC MODE**	View a graphic representation of the measuring results. Selecting **F7 TABLE MODE** or **ENTER** within the graphic mode changes to the table mode again.
F10 **RETURN**	Return to the previous screen (**ROTOR/SYSTEM** menu).
F10 **SPECIAL FUNCT**	From the **ROTOR/SYSTEM** menu, return to the **SPECIAL FUNCTIONS** menu.

6.4.4 Replacing the Photometer Lamp

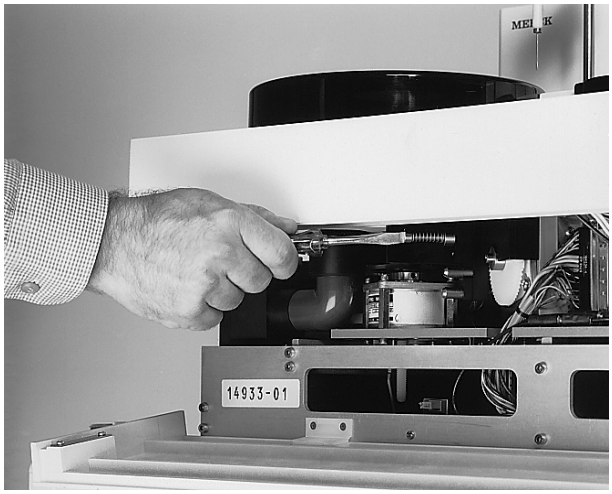
The photometer lamp has to be replaced after about 2,000 operating hours. Indications for a necessary replacement of the lamp are unusual measured results that cannot be explained. In all cases that unusual measuring results occur, check the intensity of the lamp. This is done via the **FUNCTIONAL CHECK/ADJUSTMENTS** menu (menu **SERVICE**).

Should the photometer lamp have any mechanical/ technical defects, an error message is displayed on the screen.

Attention

Be sure to switch off the instrument before replacing the lamp. Make sure that no samples are currently being processed.

1. Switch off the analyzer and remove the front cover safety screw in the middle of the device (the screw can only be seen from below).
2. Open the front of the analyzer by simply pulling at the sides of the cover. **Warning! The lamp may be hot.**
3. Loosen the top screw (of a total of three screws) with a screwdriver and remove it.
4. Carefully pull the support out towards you. **Attention! Cable connections!**



5. Remove and dispose of the lamp.
6. Carefully take the new lamp (part of the range of supply) by its top using a clean cloth. The new lamp must carefully be placed into the support and fastened.
7. Reinstall the support and fasten the screw. The lamp must be adjusted with the two screws below the top screw.

Attention

Do not touch the glass part of the lamp with your fingers. Fat, dust and humidity shorten the life of a lamp and limit its function. Be careful for movable parts when the instrument is switched on again!

8. Adjust the lamp:
   1. Select: **F5 SPECIAL FUNCTIONS**, **FUNCTIONAL CHECK/ADJUSTMENTS**, **ADJUST LAMP**.
   2. Press **TAB** or **ENTER**. A screen is displayed showing two bars representing the lamp intensity that is measured by the reference detector (Lamp) and the actual detector (Cuvette).

3. Adjust the lamp by screwing the middle and bottom screw with the two screwdrivers in such a way that the Cuvette bar on the screen is on Max. If you turn the screws carefully, you can see the bars in the display move up and down. Turn the screws until the bars reach maximum height. They should *not* show infinity signs however. The values must be at least equal to the minimum.

9. Check whether the lamp intensity is too high for each filter:
   1. Select: **F1 CHECK CUV. ABS.** The system measures the cuvette absorbance for each filter and displays the values graphically on screen. The value must be equal to or higher than the minimum value, i.e. each bar on the screen has to be at or above Min.
   2. Reduce the lamp intensity by turning the middle and bottom screw if each bar is not at or above Min.
   3. Select **F1 CHECK CUV. ABS** again and compare the heights of the bars.
   4. Repeat the procedure as often as necessary, until all filter values are equal to or higher than Min.
   5. Close the front door.
   6. Place the safety screw.
   7. Select **F10 RETURN** to quit the **ADJUST LAMP** menu.

6.4.5 Replacing syringes and syringe tips

The accuracy of the system highly depends of the state of the syringes, especially the sample syringe. It is therefore necessary to check their state regularly and replace the Teflon tips (sealing) or the complete syringes, if required. There are two clear indications for defective syringes:

- Imprecise results, with no clearly definable cause like dirt, reagents, other liquids or the photometer.
- Air bubbles in the syringes and water leaking along the syringe plunger.

1. Dismount the syringes:
   1. In the standby, inactive or halted state select: **MAIN** Menu, **F5 SPECIAL FUNC.**, **F1 ROTOR/SYSTEM**, **CHANGE SYRINGES** and press **ENTER**).
   2. Select **F1 LOWER SYRINGE** to bring both syringes to their low position.
   3. Remove the screws of the drive pins through the plunger.
   4. Carefully unscrew the syringe from the valve and push it down a little, then remove it from the instrument.

Now a new Teflon tip or a complete new syringe must be mounted. If the last Teflon tip only lasted for a short period of time it is likely, that the syringe itself is worn and must be replaced completely.

2. Replace the Teflon tips:
   1. Pull the plunger out of the glass barrel.
   2. Remove the old tip from the plunger. The small tip (sample syringe) can easily be removed with the finger nail. The large tip (reagent syringe) can be removed with a scalpel.

3. Cut the tip from top to bottom and remove it. If the O-ring under the tip is damaged, replace it as well.
4. Place the new tip upside down in the tip holder from the accessory box.
5. Hold the plunger with O-ring vertical and press the top into the Teflon tip.
6. Mount the new or renewed syringes:
   1. Fill the glass barrel with water.
7. There should be *no air bubbles* on top of the plunger now. In case of the reagent syringe the air bubble can be removed by ticking with your finger against the syringe. In case of the sample syringe the procedure must be repeated.
8. Mount the plunger over the drive pin of the pipettor, hold the syringe vertically and pull it straight up.
9. Screw the syringe in the pipettor valve. Make sure the syringe can be screwed in easily. Tighten well with your hands.
10. Select **F2 RESET PIPETT** in order to reset the pipettor and **F10 RETURN** to leave the menu. If the analyzer is now in the Halted state, reset the complete analyzer.

11. Select the **FILL/EMPTY SYSTEM** menu (from the **MAIN MENU**, press **F5 SPECIAL FUNCT.**, **F1 ROTOR/SYSTEM** and press **F1 REFILL SYSTEM**. After refilling the system the instrument is ready for use again. If there are still air bubbles visible in the tubing repeat the refilling procedure.

6.4.6 washing/filling cuvette rotor

Wash and fill the cuvette rotor as follows:

1. Stop any processing of samples.
2. Check the water supply and fill up the 10 l container, if required.
3. Select: **MAIN MENU**, **F5 SPECIAL FUNCT.**, **F1 ROTOR/SYSTEM**, **ROTOR/NEEDLE RINSE**.
4. Press **TAB** or **ENTER**.
5. Select **F2 WSH/FIL ROTOR**.

As soon as washing/filling of the cuvette rotor is finished, the system switches to the stand-by mode.

The analyzer also offers the possibility of washing the rotor only, by selecting **F1 WASH ROTOR**.

After finishing the routine all cuvettes are washed automatically; there is usually no need to perform this function manually.

The manual rotor washing procedure is only necessary, if, for any reason, the analyzer may be stopped (**ALT+F10**) while there was still reagent and/or sample in the cuvette rotor. If no new tests are performed immediately after stopping the instrument the rotor wash must be performed, otherwise the cuvette rotor will dry up and residues will stick to the rotor wall.

6.4.7 Needle rinse

During the needle rinse procedure both needles will be cleaned more intensely with the Sputofluol solution. The needle rinse procedure will take about 30 minutes.

1. Stop any processing of samples.
2. Select: **MAIN MENU**, **F5 SPECIAL FUNCT.**, **F1 ROTOR/SYSTEM**, **ROTOR/NEEDLE RINSE**.
3. Press **TAB** or **ENTER**.
4. Place a 25 ml bottle with 10% Sputofluol on the reagent wheel.
5. Select **REAGENT POSITION** and assign the position of the reagent wheel (NEEDLE RNSE).
6. Place a full sample tube with 10% Sputofluol on position no. 1 of the sample rotor.
7. Select **F3 NEEDLE RINSE**.

Installation

7.1 Hardware installation

To operate the Analyzer with a PC, the analyzer must be connected to the PC with the supplied serial cable.

1. Switch the PC and the Analyzer off.
2. Connect one end of the serial cable with COM1 on the PC.
3. Connect the other end of the serial cable with the RS232 connector on the rear side of the Analyzer.

7.2 Software installation

7.2.1 General

Install the software only by someone who is familiar with Windows.

Note

Vital Scientific N.V. does not guarantee that the program functions properly when third party programs are installed and/or active on the PC. Do not run other programs during the use of the Analyzer program.

Requirements:

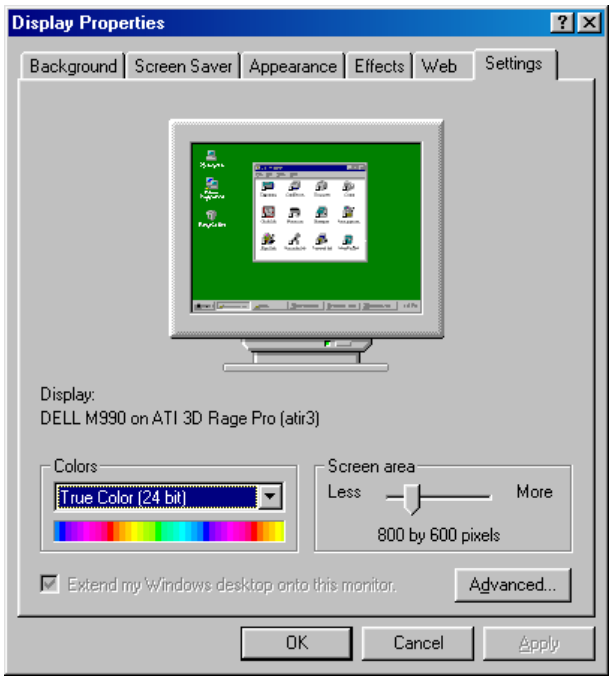
- PC as specified in section 2.9 of the manual.
- Analyzer installation disk 1, 2 and 3, or CD-rom.

7.2.2 Prepare PC

Screen area

To run the Analyzer program, set the screen area on 800 x 600 pixels.

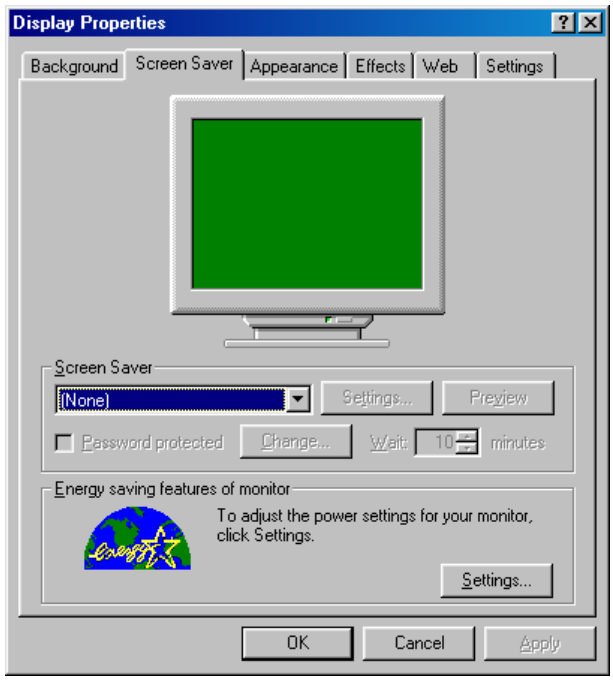
1. Run: **WINDOWS EXPLORER**
2. Select: **MY COMPUTER, CONTROL PANEL, DISPLAY**
3. Select: **Settings tab**
4. Select in the **Screen area** field: 800 x 600
5. Press: OK



Screen saver

The screen saver must be disabled to guarantee the most stable performance.

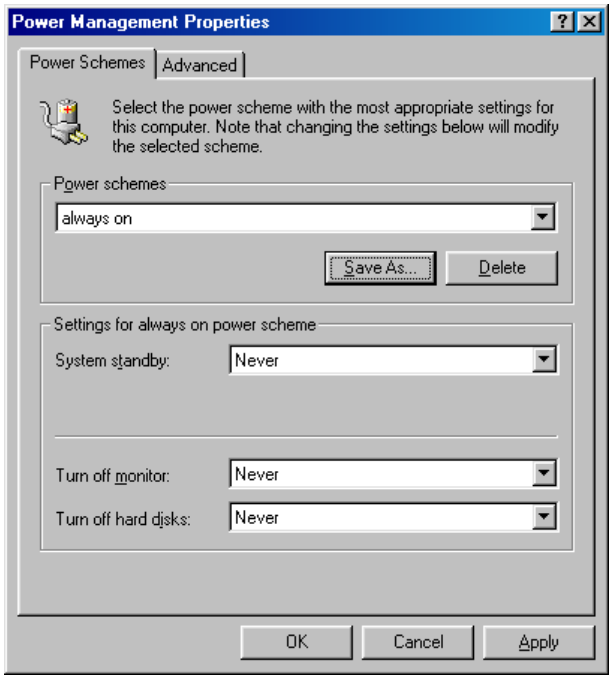
1. Run: **WINDOWS EXPLORER**
2. Select: **MY COMPUTER, CONTROL PANEL, DISPLAY**
3. Select: **Screen Saver** tab
4. Select in the Screen saver field: (None)
5. Press: **OK**



Power management

1. Run: **WINDOWS EXPLORER**
2. Select: **MY COMPUTER, CONTROL PANEL, POWER MANAGEMENT**
3. Select: **Power Schemes** tab
4. Select in the Power schemes field: **Always on**
5. Select in the System standby field: **Never**
6. Select in the Turn off monitor field: **Never**
7. Select in the Turn off hard disks field: **Never**

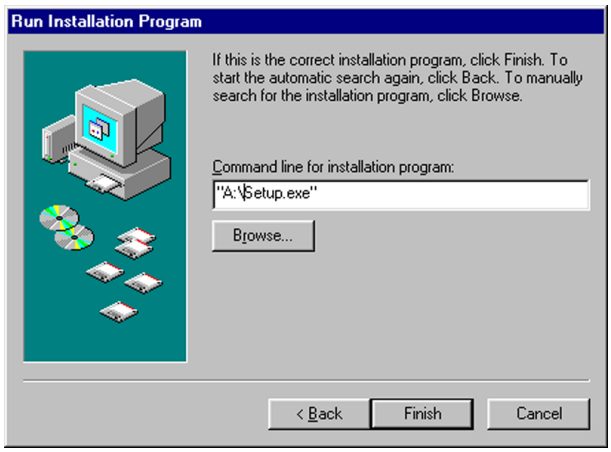
Also turn off the features for Power Saving supported in the BIOS. Refer to the manual of the PC for instructions.



7.2.3 Install software

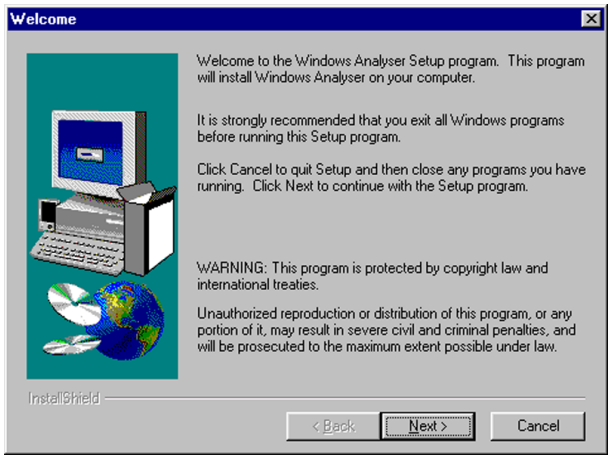
Preparation

1. Exit all programs
2. Run: **WINDOWS EXPLORER**
3. Select: **MY COMPUTER, CONTROL PANEL, ADD/REMOVE PROGRAMS**
4. Press: **Install**
5. Insert the Analyzer installation disk 1 into the floppy drive A:
6. Press: **Next**
7. Press in the Run Installation Program screen: **Finish**


Run Installation Program
If this is the correct installation program, click Finish. To start the automatic search again, click Back. To manually search for the installation program, click Browse.
Command line for installation program:
"A:\Setup.exe"
Browse...
< Back
Finish
Cancel

Installation

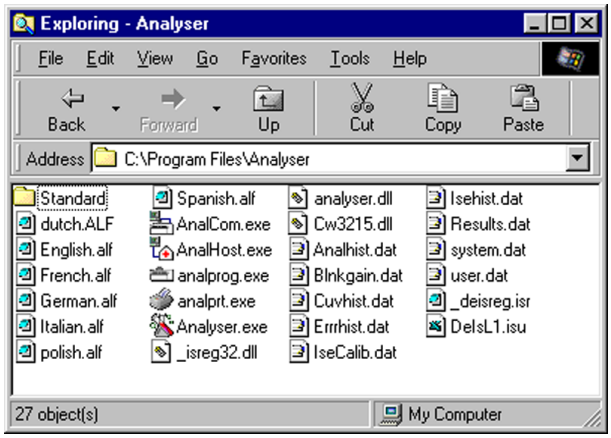
1. Press in the Welcome screen: **Next**
2. Press in the Select Program Folder screen: **Next**
3. Press in the Start Copying Files screen: **Next**
4. Change the installation disks in the floppy drive A: when requested
5. Press in the Setup Complete screen: **Finish**


Welcome
Welcome to the Windows Analyser Setup program. This program will install Windows Analyser on your computer.
It is strongly recommended that you exit all Windows programs before running this Setup program.
Click Cancel to quit Setup and then close any programs you have running. Click Next to continue with the Setup program.
WARNING: This program is protected by copyright law and international treaties.
Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under law.
InstallShield
< Back
Next >
Cancel

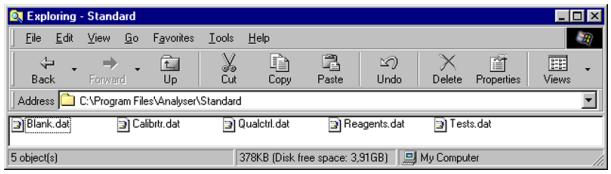
7.2.4 Files

The installation creates following directories:

- **C:\Program Files\Analyser**. The directory contains the files as shown in the figure.



- **C:\Program Files\Analyser\Standard**. The directory contains the files as shown in the figure.



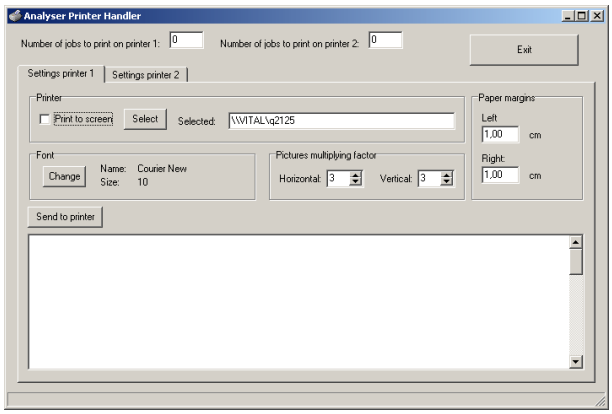
7.3 Configure software

After the Analyzer program is started, the program is ready to communicate with the Analyzer, the Printer(s) and the Host. Only change the settings of the so called Handlers with the Analyzer in the stand-by mode.

7.3.1 Configure Analyzer Printer Handler

Configure the settings of Printer 1 and/or Printer 2. The default settings are:

Parameter	Value
Print to screen	Off
Selected printer	Default Windows printer
Font	Courier New; 10 pt
Picture multi-plying factor	Horizontal: 3 Vertical: 3
Paper Margins	Left: 1 Right: 1

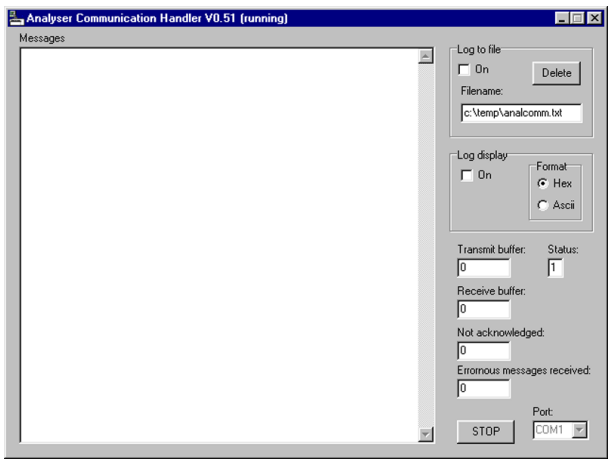


Function	Description
• **Exit**	Quits the program
• **Print to screen**	Shows the data in the preview screen. Data is not send to printer.
• **Select**	To select any printer available in Windows.
• **Send to printer**	Print the data.

7.3.2 Configure Analyzer Communication Handler

Configure the communication port between the PC and the Analyzer. The other parameters are fixed. The default settings are:

Parameter	Value
Port	COM1
Bits per second	9600
Data bits	8
Parity	None
Stop bits	1
Flow control	None



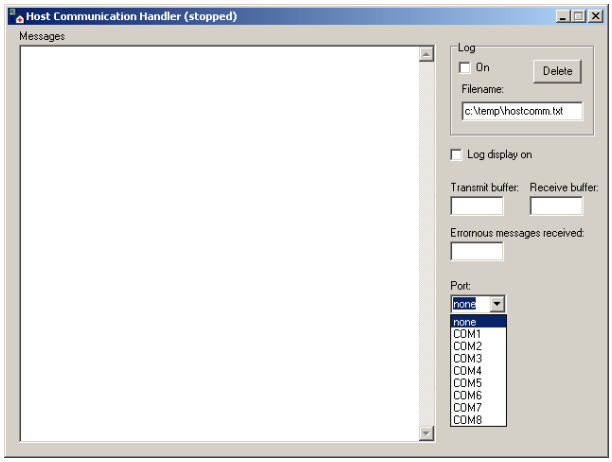
Function	Description
• **Stop/Start**	Starts or stops the communication between the PC and the Analyzer. Stop the communication to change the port number.
• **Port**	Select the port number for the communication between Analyzer and PC.

7.3.3 Configure Host Communication Handler

It is possible to start the Host Communication Handler manually from the windows **START MENU** by selecting **PROGRAMS, ANALYZER**, and **HOST COMMUNICATION** .

With the Host Communication Handler switched on, the parameters can be changed. The default settings are:

Parameter	Value
Port	None
Bits per second	9600
Data bits	8
Parity	None
Stop bits	1
Flow control	None



Function	Description
• **Port**	Select a port (1 – 8) to switch on the communication. Note: also the parameter **communication enabled** must be activated in the **INSTALLATION, COMMUNICATION** menu of the analyzer program.

7.4 Backup procedure

It is recommended to backup files every day or week. For backup, save the following files on a disk:

- The system information: all *.dat files in the folder **C:\Program Files\Analyzer**.
- The patient results: all *.txt files in the folder **C:\Program Files\Analyzer**.
- The test parameters, QC-, reagent blank-, and calibration data**: all** *.dat files in the folder **C:\Program Files\Analyzer\Standard**.

After a crash, place the files back on the locations as mentioned above.

Note: only *.dat files from the same date shall be copied back. Using *.dat files from different dates may result in a “corrupted database” error, and the *.dat files become unusable.

Appendix

8.1 Interface Description

Data formats and transmission instructions for the communication between the analyzer-PC and a host computer are described in the following.

8.1.1 RS-232 Description

The line signal definition is shown in the following table:

DB-25 pin #	Signal name		direction	remarks
7	SG	Signal Ground		
2	TX	Transmit data	output	data from analyzer-PC to host
3	RX	Receive data	input	data from host to analyzer-PC
4	RTS	Request To Send	output	*
5	CTS	Clear To Send	input	*
20	DTR	Data Terminal Ready	output	*
6	DSR	Data Set Ready	input	*
8	CD	Carrier Detect	input	not used
22	RI	Ring Indicator	input	not used

* function depending on the COM-port settings

General remarks

The analyzer-PC uses a proprietary communication protocol to connect it to a host computer. This is a normal RS232 serial interface protocol, and the main properties are given here.

- The analyzer-PC uses handshaking according to the settings of the COM-port used for the communication with the host.
- The settings of the COM-port (baud rate, start, stop and parity bits) can only be programmed in the Analyzer Host Communication Program.
- As start and stop indicators of requests and responses respectively STX and ETX are used.
- No use is made of a checksum.
- There is no initialization of a complete communication protocol as such. The host can simply send requests for reagent positions, tests, software versions etc. The analyzer-PC will respond with the corresponding answer. In order to check the communication the Echo request function can be used.
- The analyzer works in the so-called Upload mode. This means that the host sends for each individual sample a Request Sample to the analyzer-PC, which directly responds with a Request sample indication and after finishing the request with a Result.
- In case the analyzer works with more than one reagent rotor the host must send only test requests for the tests actually installed on the reagent rotor. The other tests for this sample can then be requested later.
- When the operator changes the reagent rotor of the analyzer, automatically a new Reagent Installation is sent to the host, so the host knows which tests can be requested.
- The hereafter mentioned [Physician_name] and [limit_flags] are only used when the corresponding settings in the Installation – Communication – Host Communication menu of the analyzer program are “on”.

Message	Result
Direction	analyzer → host
Format	**STX {** **R;device_id(4);** **type(1);** **Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);** **[Physician_name(20)];nr_of_tests(2);** **test_name(4);result(7);flags(22);[limit_flags(3)];units(6);** **} ETX CR LF**

Explanation

This message is sent automatically by the analyzer, if the tests of a sample are completed or if the operator presses Ctrl-F1 in the Evaluate Samples menu, in which case a result message is sent for the sample currently displayed on screen.

If in the Communications menu "Extended result:" is set to "yes", the extended result message is sent instead of the result message.

type(1) N: Normal
E: Stat
P: Pediatric
C: Control
S: Calibrator
B: Blank

FOR CONTROL:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20)];
is replaced by:
Contr_name(15);Batch_nr(10);;;[;]

FOR CALIBRATOR:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20)];
is replaced by:
Calib_name(15);;;;[;]

FOR BLANK:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20)];
is replaced by:
Blank(5);;;;[;]

The line
test_name(4);result(7);flags(22);units(6);
is repeated for each test.

flags(22): see Extended result
limit_flags(3): see Extended result

Message	Extended Result
Direction	analyzer → host
Format	**STX {** **X;device_id(4);** **type(1);** **Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);** **[Physician_name(20);]nr_of_tests(2);** **test_name(4);result(7);flags(22);[limit_flags(3);]units(6);** **reag_abs(7);raw_result(7);raw_units(6);detailed_info** **} ETX CR LF**

Explanation

type(1) N: Normal
E: Stat
P: Pediatric
C: Control
S: Calibrator
B: Blank

FOR CONTROL:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20);]
is replaced by:
Contr_name(15);Batch_nr(10);;;[;]

FOR CALIBRATOR:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20);]
is replaced by:
Calib_name(15);;;;[;]

FOR BLANK:

Sample_nr(12);Sample_name(20);date_of_birth(11);sex(1);[Physician_name(20);]
is replaced by:
Blank(5);;;;[;]

The lines
test_name(4);result(7);flags(22); [limit_flags(3);]units(6);
reag_abs(7);raw_result(7);raw_units(6);detailed_info
are repeated for each test.

FOR ISE TESTS:

reag_abs(7);
is replaced by:
;

For sample blank tests, the test_name(4) is upper/lowercase toggled.

flags(22) see below
limit_flags(3) see below

Detailed info for **mono mode**:

for kinetic:

```
K;      22 times:   used_i(1); point_i(6);
```

for twopoint:

```
T;      22 times:   used_i(1); point_i(6);
```

for endpoint monochromatic:

```
M;      endpoint_1(6);    endpoint_2(6);    42 times: ';'
```

for endpoint bichromatic:

```
B;      endpoint_1(6);    endpoint_2(6);    42 times: ';'
```

for ISE:

```
I;                                          44 times: ';'
```

Detailed info for **dual mode**:

for kinetic:

```
K;      21 times:   used_i(1); point_i(6);  2 times:  ';'
```

for twopoint:

```
T;      21 times:   used_i(1); point_i(6);  2 times:  ';'
```

for endpoint monochromatic:

```
M;
used_r_abs_1a(1);endpoint_abs_1a(6);
used_r_abs_1b(1);endpoint_abs_1b(6);
used_ep_1a(1);endpoint_1a(6);
used_ep_1b(1);endpoint_1b(6);
used_ep_2a(1);endpoint_2a(6);
used_ep_2b(1);endpoint_2b(6);
38 times: ';'
```

for endpoint bichromatic:

```
B;
used_r_abs_1a(1);endpoint_abs_1a(6);
used_r_abs_1b(1);endpoint_abs_1b(6);
used_ep_1a(1);endpoint_1a(6);
used_ep_1b(1);endpoint_1b(6);
used_ep_2a(1);endpoint_2a(6);
used_ep_2b(1);endpoint_2b(6);
38 times: ';'
```

for ISE:

```
I;                                          44 times: ';'
```

used_i(1) 0: point_i not used
1: point_i used for computation

Flags

These flags appear in a fixed order in a string. For every flag either a space is written or the respective flag. If none of the flags is true a string is sent with 22 spaces.

pos.	flag	error
1	G	general hardware error
2	R	insufficient reagent
3	#	insufficient sample
4	L	lamp error/ISE electrode not calibrated
5	U	underrange/underrange ISE electrode
6	O	overrange/overrange ISE electrode
7	u	underrange reference counter/underrange reference ISE electrode
8	o	overrange reference counter/overrange reference ISE electrode
9	T	cuvette temperature error/ISE temperature error
10	r	rerun
11	*	non linearity error
12	M	absorbance limit violation
13	D	reagent absorbance deviation error
14	W	westgard violation
15	A	calibrator limit violation
16	C	control limit violation
17	N	reference limit violation
18	a	reagent absorbance limit violation
19	I	general ISE unit error
20	X	concentration limit error
21	P	prozone error
22	E	result near cut-off

Limit flags

These flags appear in a fixed order in a string. For every flag either a space is written or the respective flag. If none of the flags is true a string is sent with 3 spaces.

pos.	flag	error
1	H	general hardware error
2	L	insufficient reagent
3	P	insufficient sample

Message	Reagent installation
Direction	analyzer → host
Format	**STX {** **I;device_id(4);** **test_name(4); (32 times)** **} ETX CR LF**

Explanation

This message is sent (automatically) by the analyzer-PC, when the operator has changed the reagent installation, the run mode or the reagent disk (menu).

For sample blank tests, the test_name(4) is left blank.

Message	Blank result
Direction	analyzer → host
Format	**STX {** **B;device_id(4);** **wavelength(3);** **cuvet_blank_val(6); (48 times)** **cuvet_av(6); cuvet_sd(6);** **lamp_av(6); lamp_sd(6);** **} EXT CR LF**

Explanation

This message is sent by the analyzer when the operator presses Ctrl-F1 in the Rotor/System/ISE - Blank Rotor menu.

Command	Echo request
Direction	host → analyzer
Format	**STX {** **E;** **} ETX**

Response	**STX {** **e;device_id(4);** **status(1); } ETX CR LF**

Explanation:

status(1) 0: success
7: failed: message length error
8: failed: overrun error
9: failed: parity, framing or break error

This message can be used as a test feature.

Command	Get software version
Direction	host → analyzer
Format	STX { V; } ETX

Response	STX {
	v;device_id(4);
	status(1);software_version(6..18);
	} ETX CR LF

Explanation:

status(1) 0: success
7: failed: message length error
8: failed: overrun error
9: failed: parity, framing or break error

Command	Get reagent installation
Direction	host → analyzer
Format	STX { I; } ETX

Response	STX {
	i;device_id(4);
	status(1);
	test_name(4); (32 times)
	} ETX CR LF

Explanation:

status(1) 0: success
7: failed: message length error
8: failed: overrun error
9: failed: parity, framing or break error

For sample blank tests or uninstalled tests, the test_name(4) is left blank (4 spaces).

Command	Get reagent test counters
Direction	host → analyzer
Format	STX { N; } ETX

Response	STX {
	n;device_id(4);
	status(1);
	reagent_test_count(5); (32 times)
	} ETX CR LF

Explanation:

status(1) 0: success
7: failed: message length error
8: failed: overrun error
9: failed: parity, framing or break error

For sample blank tests or uninstalled tests, the reagent_test_count(5) is set to 1.

Command	Request sample
Direction	host → analyzer
Format	**STX {** **Q;** **Sample_nr(1..12);** **type(1); Sample_name(0..20);date_of_birth(0..11);sex(1);** **[Physician_name(0..20);]** **request_tests(1..32);** **} ETX**

Response	**STX {** **q;device_id(4);** **status(1);** **Sample_nr(12);type(1);Sample_name(20);** **date_of_birth(11);sex(1);[Physician_name(20);]** **request_tests(32);** **} ETX CR LF**

Explanation

Sample_nr(1..12) May contain the characters 20H..7eH except 3bH (;), but may not start with 20H (space)

type(1) N: Normal
E: Stat
P: Pediatric

Sample_name(0..20) May contain the characters 20H..7eH but may not start with 20H (space)

date_of_birth(0..11) Must have the same format (European or American) as programmed in the system parameters. As separators might be used:
20H..2fH, 3aH, 3cH..40H, 5bH..60H, 7bH..7eH

Valid European Values are:
1.3.92, 01/03/1992, 1:3:92, 1|Mar|1992
Valid America values are:
3.1.92, 03/01/1992, MAR 1 92, 3:1:92, Mar|1|1992

sex(1)	M: Male F: Female P: Pediatric
request_test(1 .. 32)	a row of at most 32 '0' or '1', 0: don't request the test 1: request the test (Sample blank tests are internally in the analyzer (but not in the indication) automatically set to 1 if appropriate). If one or more Na, K or Cl tests are selected, the analyzer will measure all three and will send all three results.
status(1)	
0: success:	request created or tests added to existing request with the same sample number etc.
1: failed:	sample number already exists, but demographic information doesn't match, or request in use by the operator
2: failed:	no space for request
3: failed:	one or more tests requested, which have not been installed
7: failed:	message length error
8: failed:	overrun error
9: failed:	parity, framing or break error

Command	**Delete request sample**
Direction	host → analyzer
Format	**STX {** **D;** **Sample_nr(1..12);** **} ETX**

Response	**STX {** **d;device_id(4);** **status(1);** **Sample_nr(12);** **sample_info** **} ETX CR LF**

Explanation:

status(1)
- 0: success
- 1: failed: sample number not found, already loaded or in use by the operator
- 7: failed: message length error
- 8: failed: overrun error
- 9: failed: parity, framing or break error

sample info (only present if status is 0):

```
type(1);
Sample_name(20);date_of_birth(11);sex(1);
[Physician_name(20)];
```

Command	Ask sample result
Direction	host → analyzer
Format	**STX { R; Sample_nr(1..12); } ETX CR LF**

Response	**STX {
	r;device_id(4);
	status(1);
	Sample_nr(12);
	sample_info
	} ETX CR LF**

Explanation

status(1)

0: success: (sample ready or unloaded)
1: success: (sample loaded or still in process)
2: failed: sample number still in request buffer (not yet loaded)
3: failed: sample number not found
7: failed: message length error
8: failed: overrun error
9: failed: parity, framing or break error

sample info (only present if status is 0 or 1):

type(1);
Sample_name(20);date_of_birth(11);sex(1);
[Physician_name(20)];nr_of_tests(2);
test_name(4);result(7);flags(22);[limit_flags(3)];units(6);

type(1) N: Normal
E: Stat
P: Pediatric

The line
test_name(4);result(7);flags(22);[limit_flags(3)];units(6);
is repeated for each test.

If the result is not yet ready it is blank (‘’).

flags(22): see Extended result
limit_flags(3): see Extended result